From: Chaves, Melissa [ETHUS] <MChaves@its.jnj.com>
Sent: Wed, 08 Oct 2008 19:41:09 GMT
To: de los Reyes, Joy M. [ETHUS] <JdelosRe@its.jnj.com>; Hernandez, Jason [ETHUS] <jherna15@its.jnj.com>
Subject: MiniSling Abstract Overview & Nilsson Podcast

Great news! The Minisling Abstract Overview has been approved! I'll work with Barbara on printing 150 copies of the overview as well as making copies of all abstracts so that we can get these shipped out to the reps.

The Nilsson Podcast has been approved once I add a disclaimer stating that Nilsson is a paid consultant for ETHICON, INC.

Thanks!

Melissa

D0 99202603?

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02/08/2008

Carl Gustaf Nilsson, MD
Helsinki University Central Hospital
Haartmaninkatu 2 POB 140 00029 HUS
Helsinki, Finland 00029

Re: MASTER CONSULTING AGREEMENT

Dear Carl Gustaf Nilsson, M:

Ethicon ("COMPANY") is pleased that you have agreed to provide consulting services to COMPANY as set forth in detail on Exhibit A (the "Consulting Services"). The purpose of this letter agreement is to set forth the terms and conditions pursuant to which you will provide Consulting Services on behalf of COMPANY.

1. The term of this Agreement will start on the date that COMPANY receives a signed copy of this letter agreement from you, and extend for a period of One year(s), with automatic renewals for an additional two years. Either party may terminate this Agreement upon thirty (30) days prior written notice.

2. From time to time, COMPANY will request in writing the provision of specific Consulting Services explaining in detail the services to be provided, the date, time and location at which the Consulting Services need to be provided and other information required to determine whether you are willing to provide the specific Consulting Services. You agree to devote your best efforts to diligently provide the Consulting Services as requested by COMPANY. Nothing herein shall require you to provide any patient-identifiable information to COMPANY.

3. In consideration for your provision of the Consulting Services requested by COMPANY from time to time, COMPANY shall pay you the amounts set forth in Exhibit A. If an invoice from you is required in conjunction with the provision of Consulting Services to be provided pursuant to Exhibit A, such invoice will be provided containing the information contained in Exhibit B. You and COMPANY acknowledge and agree that this compensation represents the fair market value for the Consulting Services, has not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between you and COMPANY, and shall not obligate you to purchase, utilize, recommend, or arrange for the use of any products of COMPANY or any of its affiliates.

4. COMPANY shall reimburse you for any reasonable documented out-of-pocket expenses incurred by you which are related to your provision of the Consulting Services, provided that such out-of-pocket expenses are consistent with COMPANY's expense reimbursement policy (attached as Exhibit B). Within thirty (30) days after incurring out-of-pocket expenses related to the provision of duly authorized Consulting Services, you shall provide documentation of such expenses to:

Ethicon, Inc. Attn: Price St. Hilaire
737 US Highway 22 West
P.O. Box 151
Somerville, New Jersey 08876-0151

COMPANY shall pay you for your services and documented out-of-pocket expenses within a reasonable time after its receipt of such documentation.

Contract ID: [illegible] P.O. BOX 151, ROUTE 22 WEST, SOMERVILLE, NJ 08876-0151

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5. In preparation for, and during the course of, providing the Consulting Services, you will be provided with information concerning COMPANY including, without limitation, information regarding existing or contemplated Company products, processes, techniques, or know-how, that is confidential or proprietary and the disclosure of which would cause irreparable injury to COMPANY (collectively, the "Confidential Information"). You agree that you shall not disclose the Confidential Information to any person unless you have received prior written authorization from COMPANY. Additionally, upon termination or expiration of this letter agreement for any reason or upon the request of COMPANY, you shall promptly return to COMPANY all originals and copies of documents or other materials constituting or containing Confidential Information. Your obligations regarding the Confidential Information shall survive termination or expiration of this letter agreement.

6. In entering into this agreement, you represent and warrant that you do not have an obligation, whether express or implied, to any third party, that would interfere with, hamper or limit your ability to provide the Consulting Services or to comply with your obligations. You agree that you shall not assign your obligations under this letter agreement to any person without COMPANY's prior written approval. For the purposes of this letter agreement and the Consulting Services provided hereunder, you shall be an independent contractor and not an employee or agent of COMPANY and you shall not be entitled to participate in any benefit plans which COMPANY or its affiliates sponsor for its employees.

7. If you are a government employee, you further represent and warrant that you will comply with applicable government ethics rules and that you have secured any necessary approval of an appropriate ethics officer and, as necessary, supervisor, to enter into this agreement.

8. If you are a member of a pharmacy and therapeutics committee ("P&T Committee") of a health plan, pharmacy benefit manager or other health care provider or payor, whether public or private, you represent and warrant that you will comply with applicable ethics rules of the P&T Committee, including standards for conflict of interest, disclosure and recusal, and that you have secured any necessary approval of an appropriate ethics officer and, as necessary, P&T Committee members, to enter into this agreement.

9. You agree to ensure that the Consulting Services are provided in compliance with all applicable laws and regulations, including but not limited to: laws and regulations pertaining to the promotion of products regulated by the FDA (21 U.S.C. §§ 201, *et seq.* and its implementing regulations); laws, regulations and guidance pertaining to state and federal anti-kickback statutes (42 U.S.C. §§ 1320a-7b(b), *et seq.* and their implementing regulations) and submission of false claims to governmental or private health care payors (31 U.S.C. §§ 3729, *et seq.* and its implementing regulations); state and federal laws and regulations relating to the protection of individual and patient privacy (e.g., HIPAA); and any other laws and regulations applicable to the provision of the Services.

10. You represent and warrant that you are: (a) not excluded from a Federal health care program as outlined in Sections 1128 and 1156 of the Social Security Act (see the Office of Inspector General of the Department of Health and Human Services List of Excluded Individuals/Entities at [illegible]), (b) not debarred by the FDA under 21 U.S.C. 335a (see the FDA Office of Regulatory Affairs Debarment List at http://www.fda.gov/ora/compliance_ref/debar/); (c) not otherwise excluded from contracting with the federal government (see the Excluded Parties Listing System at http://epls.arnet.gov); and (d) if required based on the Consulting Services to be provided, duly licensed and in good standing in accordance with applicable state laws. In the event that you fail at any time to satisfy one or more of the requirements set forth in this section, COMPANY may immediately terminate this agreement.

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11. The parties acknowledge that certain states require pharmaceutical and/or device companies to disclose information on compensation, gifts or other remuneration provided to physicians and other health care professionals. COMPANY may report information about remuneration provided under this agreement, as required by law. Once reported, such information may be publicly accessible.

12. You acknowledge that the FDA, the Federal Trade Commission and other competent state or federal regulatory agencies have jurisdiction over COMPANY's products and enforce laws, regulations and policies pertaining to the promotion of medical products. You further acknowledge that such laws, regulations and policies cover representations made by you relating to the use, safety and effectiveness of COMPANY's products, and representations made by you relating to actual or potential clinical outcomes which have been observed or can be expected using COMPANY's products. You shall not make any representation relating to COMPANY's products or to COMPANY's clinical outcomes, unless such representations have been reviewed and approved in advance by COMPANY. You further agree that, in the event that the Consultant fails to observe any limitations imposed by COMPANY on such product representations or representations concerning clinical outcomes, COMPANY shall have the right to immediately terminate this Agreement.

13. You agree that the COMPANY and its designated representatives shall have the right, upon reasonable notice, to audit all of your applicable records related to the Consulting Services for the purpose of determining compliance with the compliance obligations set forth in this agreement, and any COMPANY Policies applicable to the Services provided under this Agreement and the terms of this Agreement. This right to audit shall extend throughout the term of this Agreement and for the later of a period of three years after termination of the Agreement or resolution of any disputes between the COMPANY and the Consultant hereunder.

14. The personal data collected to administer this contract is intended for use by COMPANY personnel to allow payment to be made to you. Appropriate privacy and security protections are in place to prevent disclosure of your personal data except to those employees and third parties with a business need for access to your information. Personal data collected through this system may be disclosed to other Johnson & Johnson affiliates, located in the US or elsewhere, for the purposes described above. In addition, personal data may be disclosed to third parties, located in the US and/or any other country but only to contractors we use to support our business and vendors who provide business support and technical services. Such vendors are obligated to treat personal data in accordance with this Privacy Policy, where required by applicable laws, court orders, or government regulations, or pursuant to a valid request of a governmental agency.

15. You agree that any inventions, improvements or ideas made or conceived by you in connection with or during the performance of the Consulting Services for COMPANY shall be the property of, and belong to, COMPANY. You shall, without charge to COMPANY other than reasonable payment for time involved, but at COMPANY's expense, execute, acknowledge and deliver to COMPANY all papers, including, without limitation, applications for patents, and render all assistance that COMPANY deems necessary to enable COMPANY to publish or protect such inventions, improvements and ideas by patent or otherwise.

16. You agree that during the term of this letter agreement, you shall not consult or discuss with any individual any new or existing scientific, clinical and/or related uses of, or provide services similar to the Consulting Services with regard to any product, process or equipment that is similar or related to products of COMPANY, without the prior written consent of COMPANY. Neither Party shall use the name of the other for any promotional purposes without the prior written consent of the Party whose name is to be used, nor shall either Party disclose the contents of this Agreement except as required by law. You may disclose the existence of this Agreement

consistent with any applicable conflict of interest disclosure obligations in connection with the Consulting Services to be provided.

17. Training: You shall ensure that all owners, employees and subcontractors, including but not limited to Consultant Representatives, involved in providing the Services under this Agreement, participate in training, which includes, but is not limited to, Health Care Compliance ("HCC") training and educational programs reasonably scheduled by the COMPANY. You agree to enable the COMPANY to train and periodically provide refresher training to all your new and current employees and subcontractor personnel involved in providing Services under this Agreement regarding the compliance obligations and COMPANY policies applicable to the Services provided under this Agreement.

18. You agree that during the term of this Agreement, you shall maintain insurance generally recognized as necessary and appropriate for the protection of Consultant against liabilities incurred as a result of the Consulting Services provided under this Agreement.

19. You and COMPANY agree that this letter agreement shall be governed by and interpreted under the laws of the State of New Jersey. You and COMPANY further agree that this letter agreement sets forth our entire understanding regarding the subject matter hereof, supersedes all prior agreements or understandings, whether written or oral, between you and COMPANY, and can only be modified upon the prior mutual written agreement of you and COMPANY.

20. You and COMPANY agree that any controversy or claim arising out of or relating to this Agreement or the validity, inducement or breach thereof, shall be settled by arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then pertaining (available at www.adr.org), except where those rules conflict with this provision, in which case this provision controls. Any court with jurisdiction shall enforce this clause and enter judgment on any award. The arbitration shall be held in New Jersey and in rendering the award the arbitrator must apply the substantive law of New Jersey. The arbitrator shall not award any party punitive, exemplary, multiplied or consequential damages, and each party hereby irrevocably waives any right to seek such damages. No party may seek or obtain prejudgment interest or attorneys' fees or costs.

21. Noncompliance. In the event that any part of this Agreement is determined to violate federal, state, or local laws, rules, or regulations, the parties agree to negotiate in good faith revisions to the provision or provisions that are in violation. In the event the parties are unable to agree to new or modified terms as required to bring the entire Agreement into compliance, either party may terminate this Agreement on sixty (60) days written notice to the other party.

22. Employer Certification Clause. Check either "a" or "b" below:

☐ (a) You represent that you are not an employee of any third party, including any university, and are available to do consulting on your own account, and you do not have an obligation, whether express or implied, to any third party, that would interfere, hamper or limit your ability to comply with your obligations under this Agreement or to render the professional services as described above. In conducting other activities, you will not take a position or represent interests that conflict with Ethicon's interest during the initial term or any extended term of this Agreement.

☑ (b) You represent that although you are employed by (third party) Helsinki University Central Hos. you are available to do consulting on your own account, and you do not have an obligation, whether express or implied, to any third party, including Helsinki University Central Hospital (facility or practice), that would interfere

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hamper or limit your ability to comply with your obligations under this Agreement or to render the professional services as described above. In conducting other activities, you will not take a position or represent interests that conflict with Ethicon's interest during the initial term or any extended term of this Agreement.

The undersigned is an authorized representative of Helsinki University Central Hospital (facility or practice) (authorized representative) acknowledges that (i) you may provide the professional services described above without creating any conflict with your duties as an employee of Helsinki University Central Hospit (facility or practice); (ii) you may assign to Ethicon all inventions, improvements or ideas made or conceived pursuant to the performance of the consulting services; (iii) you and your employer (facility or practice) neither has nor will have any claim of ownership for such inventions, improvements or ideas; and (iv) these acknowledgments are in conformance with Employer's Practice Policy.

Name of Institution for which you are employed:
Helsinki University Central Hospital

By: _____

Title: _____

THE REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK.

Contract ID: [illegible] P.O. BOX 151, ROUTE 22 WEST, SOMERVILLE, NJ 08876-0151

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If the terms of this letter agreement are acceptable to you, please acknowledge your agreement to the terms of this letter by countersigning the attached copy and returning it to my attention.

CONSULTANT		ETHICON	
Signature		Signature	
Name:	C. G. NILSSON	Name:	PRICE ST. HILAIRE
Title:	PROFESSOR	Title:	G. PD
Date:	4.1.2008	Date:	4-5-2008

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EXHIBIT A
SERVICES AND FEES

A Consultant agrees to perform the Services below for which the "Yes" box is checked, for the compensation set forth therein.

1. COMPANY-Sponsored Speaker Programs. ☐ Yes ☑ No
Consultant shall present scientific, clinical and related professional information by speaking at COMPANY-sponsored seminars and meetings as requested by COMPANY, subject to Section 4. Consultant shall disclose to attendees that he is being compensated by COMPANY for the presentation. Consultant shall make such presentations on _____ occasions. The presentation will review

_____

For each such speaking engagement, COMPANY shall pay Consultant _____ per _____ hour day plus reasonable out-of-pocket expenses. For one time events please complete:
Date: _____
Time: _____
Location: _____

2. COMPANY Sales Training Presentations. ☐ Yes ☑ No
Consultant shall participate and make educational presentations at COMPANY sales training sessions and sales meetings for COMPANY's sales force on _____ occasions on dates _____, times _____ and subjects

_____

mutually agreed upon by the Parties. For each such engagement, COMPANY shall pay Consultant _____ per _____ hour day plus reasonable out-of-pocket expenses.

3. Product Review Meetings. ☐ Yes ☑ No
Consultant shall participate in

_____

product review meetings concerning COMPANY products at times and places mutually agreed upon by the Parties. COMPANY shall pay Consultant _____ per hour, up to _____ per _____ hour day plus reasonable out-of-pocket expenses.

4. Preceptorship / Surgical Training. ☐ Yes ☑ No
Consultant shall allow visiting surgeons and visiting COMPANY sales representatives to observe surgical procedures involving the practice of

_____

the clinical uses of

_____

and to consult with Consultant regarding such procedures applicable patient confidentiality and consent requirements. In particular, Consultant agrees that it shall secure appropriate patient consent to the presence of any third party during surgical training programs as necessary. Consultant shall allow such visits on up to _____ occasions, and COMPANY shall pay Consultant _____ for each such session per _____ hour day. For one time events please list:
Date: _____
Time: _____
Location: _____
Employees present:

_____

_____

_____

_____

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5. Advisory Boards. ☑ Yes ☐ No
Consultant shall participate in US Preceptor Summit - Salt Lake City
Advisory Board meetings concerning COMPANY Products or other topics designated by COMPANY. COMPANY shall pay Consultant $2,000 per 8 hour day for each such meeting, including preparatory and follow-up, plus reasonable out-of-pocket expenses

6. Product Evaluations, Written Materials, and Market Reviews.
☐ Yes ☑ No
Upon request of COMPANY, Consultant shall prepare written evaluations of COMPANY Products and summaries of clinical and market developments potentially affecting COMPANY Products, and shall prepare or review clinical, sales or marketing materials relating to COMPANY products. COMPANY shall pay Consultant _____ per hour for such materials, up to a maximum amount negotiated by the Parties.

7. Product / Market Research ☐ Yes ☑ No
COMPANY is pleased you have agreed to participate in a Product/Market Research for the company for purposes of evaluating, discussing, and advising the company regarding new and/or existing clinical or market developments, techniques and/or strategies involving _____
COMPANY shall pay Consultant _____ per _____ hour day for each such meeting. Additionally, the Company shall reimburse you for any reasonable documented out-of-pocket expenses incurred by you which are related to your participation at the meeting, provided that such out-of-pocket expenses are consistent with the Company's expense reimbursement policy. The date, time, and location of the meeting are as follows:
Date: _____
Time: _____
Location: _____

8. Other ☐ Yes ☑ No
Consultant shall perform such other Services designated below, for _____ per hour:
Description of Services:
_____
_____
_____
_____
_____
_____
_____
_____

8 The Parties agree that compensation paid to Consultant shall not exceed $5,000 per year, except as may be mutually agreed in writing by the Parties

(original)

LICENSE AND SUPPLY AGREEMENT

LICENSE AND SUPPLY AGREEMENT ("Agreement") dated as of February 13, 1997, between **JOHNSON & JOHNSON INTERNATIONAL,** a company with its principal office at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933 U.S.A. ("JJI"), and **MEDSCAND MEDICAL A.B.**, a company with its principal office at Stadiongatan 65, S 20074, Malmo, Sweden ("Medscand").

WHEREAS, Medscand and JJI desire to enter into this Agreement which will set out the terms and conditions under which (i) Medscand will supply to JJI the Products (as defined below), (ii) JJI shall, directly or through its affiliates be marketing and distributing the Product and (iii) Medscand is granting JJI a worldwide exclusive right and license to the Technology (as defined below);

NOW THEREFORE, in consideration of the mutual covenants and consideration set forth herein, the parties hereto agree as follows:

SECTION 1.

DEFINITIONS

1.1 The following terms as used in this Agreement shall have the following definitions:

(a) **"Affiliate"** shall mean, in relation to either party hereto, (a) any company or other entity in which the relevant party directly or indirectly holds more than 50% of the voting securities, (b) any company or other entity ("Holding Company") which holds directly or indirectly more than 50% of the voting securities of the relevant party, (c) any other company or other entity in which more than 50% of the voting securities is directly or indirectly held by any Holding Company of the relevant party or (d) any company or other entity in which the relevant party directly or indirectly holds less than 50% of the voting securities but has management control of such company or entity in that it has the ability to appoint and remove the majority of the directors of such company or entity.

(b) **"Bankruptcy Event"** shall mean the person or entity in question becomes insolvent, or voluntary or involuntary proceedings by or against such person or entity are instituted in bankruptcy or under any insolvency law, or a receiver or custodian is appointed for such person or entity, or proceedings

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are instituted by or against such person or entity for corporate reorganization or the dissolution of such person or entity, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing, or such person or entity makes an assignment for the benefit of its creditors, or substantially all of the assets of such person or entity are seized or attached and not released within sixty (60) days thereafter.

(c) **"Change in Control"** shall mean:

i. the liquidation or dissolution of Medscand or the sale or other transfer by Medscand (excluding transfers to subsidiaries) of all or substantially all of its assets; or

ii. the occurrence of a tender offer, stock purchase, other stock acquisition, merger, consolidation, recapitalization, reverse split, sale or transfer of assets or other transaction, as a result of which any person, entity or group (a) becomes the beneficial owner, directly or indirectly, of securities of Medscand representing more than 50% of the ordinary shares of Medscand or representing more than 50% of the combined voting power with respect to the election of directors (or members of any other governing body) of Medscand's then outstanding securities, (b) obtains the ability to appoint a majority of the Board of Directors (or other governing body) of Medscand, or (c) obtains the ability to direct the operations or management of Medscand or any successor to Medscand's business.

(d) **"Claims"** shall have the meaning ascribed in Section 4.8.

(e) **"Consulting Agreement"** shall mean that certain Consulting and Technology Transfer Agreement in the form attached as an exhibit to this Agreement.

(f) **"Clinical Trials"** shall mean any systematic study in humans undertaken to verify the safety and/or efficacy of the Product under its intended conditions of use.

(g) **"E.E.A."** shall mean European Economic Area, as recognized as of the date of this Agreement.

(h) **"JJI Inventions"** shall have the meaning ascribed in Section 3.8(b).

(i) **"Evaluation Right"** shall have the meaning ascribed

in Section 3.7.

(j) **"Event of Default"** shall have the meaning ascribed in Section 5.6(a).

(k) **"FDA"** shall mean the U.S. Food and Drug Administration.

(l) **"Force Majeure Notice"** shall have the meaning ascribed in Section 6.8(b).

(m) **"Holding Company"** shall have the meaning ascribed in Section 1.1(a).

(n) **"Improvements"** shall mean such Know-How, special knowledge, technical or other information, whether or not patented or patentable, owned, controlled or acquired by Medscand during the term of this Agreement, related to the manufacture, development, use or sale of the Product, which is based upon any of the Patents or Know-How of Medscand as of the date of this Agreement (including, but not limited to, formulas, processes, data, techniques, methods, apparatuses, components, technology, materials and compositions).

(o) **"Joint Inventions"** shall have the meaning ascribed in Section 3.8(c).

(p) **"Know-How"** shall mean all know-how owned, controlled or acquired by Medscand at any time prior to or during the term of this Agreement, including without limitation, processes, techniques, methods, products, software (including the source code related thereto), components, apparatuses, or chemical materials and other materials and compositions, which are related to the manufacture, development, use or sale of (i) any Product or (ii) any products which can be used for the surgical treatment of stress urinary incontinence.

(q) **"Manufacturing Plan"** shall have the meaning ascribed in Section 4.2(a).

(r) **"Medscand Inventions"** shall have the meaning ascribed in Section 3.8(a).

(s) **"Offer"** shall have the meaning ascribed in Section 3.7(c).

(t) **"Other Product"** shall mean a product whose manufacture, use or sale would infringe a Valid Claim of a Joint Patent.

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(u) **"Patent(s)"** shall mean (i) all the patents and applications for patents, if any, that are identified in Exhibit B, any foreign counterparts thereof, as well as all continuations, continuations-in-part, divisions and renewals thereof, all patents which may be granted thereon, and all reissues, reexaminations, extensions, patents of addition and patent of importation thereof, (ii) any Medscand patent application related to or based on any Know-How that is developed during the term of this Agreement, and any division, continuation or continuation-in-part of any such application and any patent which shall issue based on such application, divisional, continuation or continuation-in-part, and any patent which is a reissue or extension thereof or a patent of addition to any such patent and (iii) any other patents or patent applications which are owned or controlled by Medscand and which may be necessary to make, have made, use, distribute or sell any of the Products.

(v) **"Process Description"** shall mean, with respect to a Product, good manufacturing procedures (including, but not limited to, ISO 9000 series procedures) with respect to such Product, as well as such other know-how, technical specifications, instructions, processes and other intellectual property and information Medscand shall possess and as shall be necessary in order to allow JJI to manufacture and/or have manufactured for it the Product. Such Process Descriptions shall be sufficiently clear and detailed that it can be readily followed and carried out by a skilled person.

(w) **"Product"** shall mean (i) Medscand/Professor Ulmsten's intra-vaginal slingplasty device for treating surgically stress urinary incontinence, which device includes a Prolene® mesh covered by a removable plastic sheet and swaged on two metallic needles (the "Needles") attachable to a handle, (ii) the handle which can be attached to the Needles (the "Handle"), and (iii) any Improvements thereto.

(x) **"Purchase Price"** shall have the meaning ascribed in Section 4.3(a).

(y) **"Regulatory Approval"** shall mean, with respect to any country, filing for and receipt of all regulatory agency registrations and approvals (including, but not limited to, approvals of all final Product labelling) required for the marketing and sale of a Product for the indication for which it is being marketed in such country.

(z) **"Regulatory Filings"** shall mean all applications, filings, materials, studies, data and documents of any nature whatsoever filed with, or prepared in connection with, any Regulatory Approval process in any country or territory.

(aa) **"Specifications"** shall have the meaning ascribed in Section 4.1(b).

(ab) **"Technology"** shall mean the Product, any Improvements, and all Patents and Know-How.

(ac) **"Territory"** shall mean the entire world.

(ad) **"Valid Claim"** shall mean a claim in any unexpired patent which has not been held invalid by a non-appealed or unappealed decision by a court or other appropriate body of competent jurisdiction.

SECTION 2.

DISCLOSURES

Medscand expressly understands and acknowledges that JJI and its Affiliates are currently and in the future will evaluate other business opportunities and products in the urinary incontinence market. JJI (and/or its Affiliates) in its sole discretion may participate in these markets alone or in other business or research arrangements with third parties, both now and during the term of this Agreement. Medscand acknowledges that the consideration and other terms and conditions provided under this Agreement is complete and adequate consideration for Medscand entering this Agreement.

SECTION 3.

DEVELOPMENT/LICENSE AGREEMENT

3.1 **Grant of Exclusive License Rights.** Subject to the terms and conditions of this Agreement, Medscand hereby grants to JJI an exclusive, worldwide right and license, with the right to grant sublicenses, to the Technology for purposes of making and having made (subject to Medscand's rights to supply Products pursuant to Section 4 hereof), marketing, leasing, using, distributing and selling products (including the Products) and any Improvements based on such Technology.

3.2 **Exclusivity Protections.**

(a) During the term of this Agreement and except as specifically permitted in this Agreement:

(1) Medscand shall not grant or license to or otherwise permit any third party to (i) use, make, have made, lease, sell or otherwise commercialize the Product or (ii) use the Technology to make, have made,

use, lease or sell or otherwise commercialize the Product or any product which competes with the Product.

(2) Medscand shall cooperate with JJI and take all actions reasonable and appropriate to prohibit and prevent third parties from making, using, leasing or selling any product obtained from or through Medscand in competition with any Product, including, without limitation, the termination of licenses and contract rights.

(b) JJI shall have the right to grant sublicenses to any Affiliate or to any third party with respect to any rights conferred upon JJI under this Agreement; provided, however, that any sublicense shall be subject in all respects to the same terms, conditions and provisions contained in this Agreement.

3.3 **Advisory Board**. During the development of, and pursuit of Regulatory Approval for, the Product or any Improvement hereunder, the parties agree to form an Advisory Board made up of not more than four (4) individuals each from Medscand and JJI (or its Affiliates), which shall include Medscand's Managing Director and a Vice President of JJI (or one of its Affiliates). The Advisory Board will meet from time to time to discuss the details of the development and Regulatory Approval process for all Products. The location, time and length of such meetings shall be agreed to by the parties. The Advisory Board shall alternate the location of its meetings between the facilities of each of the parties or by mutual agreement meet at either facility or telephonically. The Advisory Board shall have executive authority to direct the course of development of the Products or Improvements, as well as to direct the course of the Regulatory Approval process therefore. Necessary adjustments in the program shall, to the extent possible, be mutually agreed upon; provided, however, that in the event of a disagreement, Medscand shall have final decision making authority over any development issues, and JJI shall have final decision making authority over any regulatory issues.

3.4 **Development; Regulatory Approval**.

(a) Medscand shall, with the cooperation and reasonable assistance of JJI, conduct those studies and undertake such other steps and actions as shall be reasonably necessary (including, but not limited to, any testing required in connection with obtaining any Regulatory Approvals) to obtain in a prompt fashion Regulatory Approval of the Product in the E.E.A. Medscand will also assist JJI in conducting the necessary studies and trials for obtaining Regulatory Approval in the U.S., such assistance to include the provision to JJI of all studies, data

and other materials in Medscand's possession or control related to the Products. If Medscand ceases active pursuit of Regulatory Approval in the E.E.A., JJI shall be given notice of Medscand's decision to cease active pursuit of Regulatory Approval in the E.E.A. and JJI shall thereafter be entitled to take such steps and actions as shall be necessary to obtain such Regulatory Approval. Medscand acknowledges that JJI's right to pursue Regulatory Approval in no way relieves Medscand of its obligations to pursue regulatory approval for the Products under this Agreement.

(b) Medscand, as legal manufacturer of the Products, shall file in its own name the Regulatory Filings for Regulatory Approval of the Product in the E.E.A. Copies of all such Regulatory Filings shall be provided to JJI within fourteen (14) days after each such submission, and JJI shall be permitted to use and cross-reference such Regulatory Filings.

(c) JJI shall have responsibility for filing in its own name (or that of its Affiliates) the Regulatory Filings for Regulatory Approval of the Product in the U.S. Copies of all such Regulatory Filings shall be provided to Medscand within fourteen (14) days after each such submission. Medscand shall provide to JJI all such assistance and information as shall be reasonably necessary for JJI to make such Regulatory Filings.

(d) JJI shall have the right, but not the obligation, to pursue regulatory approval of the Products in those territories outside the U.S. and the E.E.A. In the event JJI pursues such approvals, Medscand shall provide to JJI such assistance and other information as shall be reasonably necessary for JJI to obtain such approvals. All such approvals, permits and licenses shall be in JJI's (or its Affiliates) name unless otherwise required by law.

3.5 **Improvements**. From time to time, JJI may request that there be improvements and/or changes to the Specifications should JJI determine such improvements or changes are necessary or desirable. Such changes or improvements shall be funded by Medscand; provided, however, that if any such changes or improvements increase Medscand's production costs in excess of ten percent (10%), Medscand and JJI shall enter into good faith discussions to determine an equitable adjustment to the Purchase Price to take into account such increased costs.

3.6 **Milestone Payments**. In consideration of Medscand entering into this exclusive License and Supply Agreement, and of Medscand's reaching certain milestones relating to the Products, JJI shall pay to Medscand the following payments:

(a) a payment in the amount of US$200,000, due within five (5) business days of the execution of this Agreement;

(b) a payment in the amount of US$400,000, due on February 28, 1997; provided, however, that in the event the Clinical Trials as specified in Exhibit C have not been completed by such date, then such amount shall not be due until completion of the Clinical Trials;

(c) a payment in the amount of US$400,000, due within fourteen (14) days after receipt by JJI of a copy of Medscand's CE Marking certification for the Product.

Notwithstanding the foregoing Sections 3.6(b) and (c), the payments contemplated by such sections shall not be due or payable until completion of the conveyance of the Intellectual Property to Medscand in accordance with the Consulting Agreement.

3.7 **Evaluation Rights and Rights of First Offer**.

(a) JJI shall have a right to review and evaluate any new or additional medical device or technology which Medscand creates or develops ("New Product") relating to the treatment of urinary stress incontinence during the term of this Agreement. Medscand shall promptly notify JJI in writing of any New Product, such notice to include a reasonably detailed description of the New Product which would enable JJI to make such an evaluation. JJI shall exercise such evaluation right by providing to Medscand a written notification of such exercise within thirty (30) days after receipt of Medscand's notice with respect to such New Product. Upon exercise of the Evaluation Right, Medscand shall provide to JJI such studies, patent information, descriptions of technology, product samples and other materials JJI shall reasonably request in order for it to conduct a review of the New Product.

(b) JJI shall be entitled to review such materials for a period of six months ("Review Period") from the date it notifies Medscand that it wants to exercise its evaluation right. Upon expiration of such six month review period, JJI shall return to Medscand all confidential and proprietary materials provided to JJI in connection with its exercise of the evaluation right.

(c) Upon expiration of any such Review Period, JJI shall have the right of first offer with respect to such New Product. Such right shall be exercised within thirty (30) days after the expiration of the applicable Review Period. In order to exercise such right of first offer, JJI shall provide to Medscand a written, reasonably detailed offer (the "Offer") for

the rights to the New Product.

(d) Medscand shall have one hundred and twenty (120) days from receipt of the Offer to either accept such Offer or obtain an offer from a third party (the "Third Party Offer") which is superior to the Offer. In the event Medscand obtains a Third Party Offer, it shall so notify JJI and provide to JJI the details of such Third Party Offer. JJI shall have a period of forty-five (45) days in which to either agree to meet the terms and conditions of the Third Party Offer or to determine not to further pursue the New Product.

(e) In the event JJI agrees to meet the terms and conditions of the Third Party Offer, Medscand and JJI shall promptly enter into definitive documentation for the New Product, on the basis of the Third Party Offer. If JJI does not elect to meet the terms of the Third Party Offer Medscand shall be free to enter into agreements with such third party on the terms and conditions of the Third Party Offer.

(f) In the event that Medscand does not enter into definitive documentation for the New Product within sixty (60) days after the expiration of such forty-five (45) day period, then the provisions of this Section 3.7 shall apply to any further actions with respect to such New product.

3.8 Inventions

(a) Title to any inventions or discoveries made by Medscand employees or agents without inventive contribution of JJI employees or agents, based on any Medscand Know-How related in any way to a Product or developed during Medscand's performance under this Agreement ("Medscand Inventions") shall belong to Medscand. Medscand may file patent applications for Medscand Inventions in its own discretion and at its own expense.

(b) Title to any inventions and discoveries made by JJI employees or agents without inventive contribution by Medscand employees or agents and conceived or first reduced to practice under this Agreement (hereinafter, "JJI Inventions") shall belong to JJI. JJI may file patent application(s) for JJI Inventions in its own discretion and at its own expense.

(c) Title to any inventions or discoveries made jointly by employees or agents of Medscand and JJI and conceived or first reduced to practice under this Agreement (hereinafter, "Joint Inventions") shall belong to Medscand and JJI jointly, i.e. each shall own an undivided one-half interest therein. Medscand and JJI shall keep each other fully and promptly informed as to such Joint Inventions. After Joint Inventions are reduced to practice

JJI shall have primary responsibility for filing, prosecuting and maintaining any U.S. patent application(s) or patent(s) and foreign counterpart thereof for Joint Inventions, but shall give full consideration to Medscand's recommendations including selection of attorney(s). The patent expenses for Joint Inventions shall be borne equally by JJI and Medscand, but either may, by giving timely notice to the other, withdraw from further participation in the filing, prosecution and/or maintenance of any such patent application(s) or patent(s)and shall not be liable for any expenses incurred after written notice is given. If either party does not elect to file, prosecute or maintain any such patent application(s) or patent(s) in a country or countries, or after electing to participate in the filing, prosecution and/or maintenance on such Joint Inventions in a country or countries, does not pay its share of the expenses within one hundred twenty (120) days of written notification of expenses being due, the other party, in its sole discretion, shall have the right to file, prosecute or maintain at its expense on a country by country basis each such patent application(s) and patent(s). In that event, the party paying all the costs and expenses shall cease to have any further obligation to pay a royalty to the other party on such patent application(s) or patent(s) in such country until the party recovers half the total costs and expenses of such patent filings, prosecution and maintenance.

(d) Each party shall require its employees or agents responsible for conducting research in performance of this Agreement to keep contemporaneous records of their results and findings in sufficient detail to document any inventions of discoveries made by such employees and agents under this Agreement in bound notebooks (which notebooks shall be reviewed and signed by a witness on a regular basis).

(e) Medscand and JJI will cooperate in a timely manner to prepare, review and execute patent applications and all such further papers, as may be necessary to enable the parties to protect Joint Inventions by patent in any and all countries and to vest title to said patent application(s) and patent(s) and assist in any patent office or agency proceedings.

(f) If either party wishes to practice a patented Joint Invention outside the grant provided to JJI under Section 3.1, the party practicing the patented Joint Invention will pay a royalty of three percent (3%) of the Net Sales of any Other Product unless said patent is licensed under this Agreement or used solely by a party in fulfilling its obligations under this Agreement; provided, however, that if a party seeks to practice a patented Joint Invention for which it did not pay its share of the cost and expenses, such party shall have to reimburse the

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party that paid the costs and expenses one-half of the costs and expenses incurred in the country or countries in which the party seeking to practice the Joint Invention will make, have made, use, lease or sell the Other Product prior to practicing the patented Joint Invention.

(g) The party paying the royalty shall keep accurate books and records of all payments due to the party owed the royalty. Said books of account shall be kept at the party paying the royalty's principal place of business or the principal place of business of an appropriate Affiliate or sublicensee to which this Agreement relates.

(h) The party owed the royalty shall have the right to nominate an independent accountant acceptable to and approved by the party paying the royalty (which approval shall not be unreasonably withheld) who shall have access to the records of the party paying the royalty during reasonable business hours for the purpose of verifying, at the party owed the royalty's expense (except as provided below), the royalty payable as provided for in this Agreement for the two (2) preceding years, but this right may not be exercised more than once in any year. The party owed the royalty shall solicit or receive only information relating to the accuracy of the royalty report and the royalty payments made. The party paying the royalty shall be entitled to withhold approval of an accountant which the party owed the royalty nominates unless the accountant agrees to sign a confidentiality agreement with the party paying the royalty which shall obligate such accountant to hold the information he receives from the party paying the royalty in confidence, except for information necessary for disclosure to the party owed the royalty necessary to establish the accuracy of the royalty reports. Any underpayment of royalty shall be paid within thirty (30) days after the delivery of a detailed written accountants report to the party paying royalty. Any overpayment of royalty shall be credited to the next royalty payment due from the party paying the royalty. If no further royalty payments will be due then a refund will be made within thirty (30) days of the audit.

(i) In the event that a party owes a royalty, such party shall deliver to the party owed the royalty written reports of Net Sales during the preceding calendar quarter, on or before the thirty (30th) day following the end of each calendar quarter. In the event that a party owes royalty for sales made by its Affiliate or its sublicensee, such party shall deliver to the party owed the royalty written reports of Net Sales for such Affiliate or sublicensee during the preceding calendar quarter, on or before the ninetieth (90th) day following the end of each calendar quarter. Such reports shall include a calculation of the earned royalty due and shall be accompanied by the monies

due.

3.9 **Patents** Medscand shall have responsibility for filing and maintaining all Patents at its own expense (including patent applications for Medscand Inventions) and shall keep JJI fully and promptly informed as to both the Medscand Inventions and the filing, prosecution and maintenance of such Patents. Unless otherwise agreed by the parties, Medscand shall only have the obligation to file and maintain Patents in the following countries: USA, Japan, Germany, France, Italy, U.K., Russia, India, Sweden, Denmark and Spain. If Medscand does not elect to file, prosecute or maintain any such Patents, Medscand shall so notify JJI and JJI shall, in its sole discretion, have the right to require that Medscand file, prosecute or maintain at JJI expense on a country by country basis such Patents. In that event, JJI shall pay the costs and expenses of and manage the prosecution of such Patents and JJI shall be entitled to deduct such costs from the Purchase Price for any Products ordered with respect to such country. With respect to (i) all other countries other than those specified in this paragraph as being those where Medscand shall have filing and maintenance responsibility and (ii) such other countries where Medscand in its sole discretion elects to file and maintain Patents, JJI shall have the right, but not the obligation, to file for any and all Patents in such other countries at its own expense and in its own name, and Medscand shall provide all such assistance and cooperation to JJI as shall be reasonably necessary in order for it to make such filings and maintain such Patents.

3.10 **Infringement**.

(a) If, as a result of the manufacture, use or sale of any Product in any country of the Territory, Medscand or JJI and/or its Affiliate is sued for patent infringement or threatened with such a lawsuit or other action by a third party, Medscand and JJI shall meet to analyze the infringement claim and avoidance of same. If it is necessary to obtain a license from such third party, Medscand and JJI in negotiating such a license shall make every effort to minimize the license fees and/or royalty payable to such third party. If JJI shall be obligated to pay a license fee and/or royalty, then JJI shall have the option to either (i) deduct such license fee and/or royalty from the Purchase Price for the Products (such deduction not to exceed 20% of the Purchase Price for each unit of Product) or (ii) terminate this Agreement as to such affected country or countries upon thirty (30) days notice to Medscand. Any license fee and/or royalty due as the result of using JJI's patents or know-how to manufacture, use or sell a Product shall be borne by JJI.

(b) In the event that there is infringement of a Patent

involving the Product by a third party, Medscand and JJI (or its Affiliate or sublicensee) shall notify each other in writing to that effect, including with said written notice evidence establishing a case of infringement by such third party. Medscand shall bear all the expenses of any suit brought by it and shall retain all damages or other monies awarded or received in settlement of such suit. JJI and/or its Affiliates will cooperate with Medscand in any such suit or shall have the right to consult with Medscand and be represented by its own counsel at its own expense. If after the expiration of one hundred eighty (180) days from the date of receipt of said notice of infringement Medscand has not overcome the case of infringement, obtained a discontinuance of such infringement, or brought suit against the third party infringer, then JJI shall have the right, in its sole discretion, but not the obligation to bring such suit at its own expense and in its own name, if possible. JJI shall bear all the expenses of any suit brought by it and shall retain all damages or other monies awarded or received in settlement of such suit; provided, however, that if such damages or other monies exceed JJI's expenses incurred in connection with such suit, such excess amount shall be shared equally between the parties. Medscand will cooperate with JJI in any such suit and shall have the right to consult with JJI and be represented by its counsel at its own expense. JJI shall have the right to offset any such expenses involved in any such suit against the Purchase Price for any Products; provided, however, that JJI shall amortize such expenses in a manner so that it may not reduce the per unit Purchase Price by an amount of no greater than twenty percent (20%).

SECTION 4.

SUPPLY AGREEMENT

4.1 **Exclusive Supply of Products; Specifications.**

(a) Except as specifically provided by the provisions of this Agreement, Medscand shall be the exclusive supplier of the Products to JJI during the term of this Agreement, and Medscand shall exclusively supply the Product to JJI during the term of this Agreement.

(b) No less than thirty (30) days prior to the placement of the first order for each Product under this Agreement, the parties shall agree upon the final specifications ("Specifications") for such Product. Such Specifications shall become a part of this Agreement and be attached as part of Exhibit A hereof.

(c) All Product supplied to JJI hereunder shall be

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supplied in a finished and non-sterile form, in packaging which is suitable for delivery to the ultimate end-user of the Product. The packaging requirements shall be specified in the Specifications.

4.2 **Production Facilities and Capabilities.**

(a) Within thirty (30) days after the execution and delivery of this Agreement, Medscand shall submit to JJI its one and two year manufacturing capability plan (the "Manufacturing Plan") for completing implementation of procedures and facilities for producing the Products which satisfy both the volume, specifications and other supply requirements of Section 4 of this Agreement. JJI shall promptly review the Manufacturing Plan and discuss with Medscand changes, if any, required to meet such provisions. Notwithstanding JJI's review of the Manufacturing Plan, it is expressly acknowledged that Medscand shall be solely responsible for complying with its obligations under Section 4.

(b) JJI shall have the right to audit or have audited the manufacturing facilities which Medscand is going to use to manufacture the Products to confirm that such facilities are adequate to meet the requirements of the Manufacturing Plan and the requirements of Section 4 of this Agreement. If such audits reveal that the manufacturing facilities either do not satisfy the requirements of the Manufacturing Plan or are not adequate to meet the requirements of Section 4 of this Agreement, then JJI shall provide written notice of such fact, which notice shall contain in reasonable detail the deficiencies found in the manufacturing facilities and, if practicable, those steps Medscand should undertake in order to remedy such deficiencies.

(c) In the event such deficiencies are not capable of being remedied by Medscand within ninety (90) days of such notice, then Medscand and JJI shall discuss in good faith alternative manufacturing arrangements (which could include JJI or a designated third party providing the manufacturing facilities) which will enable the Products to be supplied in accordance with this Agreement. If the parties are unable to reach agreement within sixty (60) days as to such alternative manufacturing arrangements, then JJI shall have the right to terminate the supply provisions of Section 4 of this Agreement upon written notice to Medscand, in which event (a) JJI shall be entitled to manufacture or have manufactured the Products, and (b) Medscand shall provide such assistance and other information as shall be necessary in order for JJI to manufacture or have manufactured the Products. If JJI determines to take over manufacturing of the Product, JJI shall pay to Medscand the amount of US$45 per unit of Product which is so manufactured and sold by JJI.

(d) In order to ensure that Medscand shall be able to meet its supply obligations under this Agreement, Medscand shall maintain at all times in a facility which is physically separate from its primary manufacturing facility inventory levels of the Products of no less than ninety (90) days forecasted supply.

4.3 **Orders, Prices and Terms.**

(a) The purchase price ("Purchase Price") for each Product purchased from Medscand shall be as follows:

(1) Needles shall be purchased for the aggregate price of (A) US$68 per unit, plus (B) the net payments, if any, to JJI for any subcontracted components and services acquired from JJI in connection with the Product ("JJI Costs"), plus (C) five percent (5%) of the aggregate per unit JJI Costs; and

(2) Handles shall be purchased for US$100 per unit.

(b) On and after January 1, 1999, the Purchase Price will be revised on an annual basis in accordance with the inflation index specified on Exhibit D.

(c) All shipments of Products shall be F.O.B. Medscand's manufacturing facility in Malmo, Sweden, and shall be accompanied by a packing slip which describes the Products, states the purchase order number and shows the shipment's destination.

(d) The terms of this Agreement shall govern and supersede any other conflicting terms or conditions contained in any purchase order, purchase order release, confirmation, acceptance or any similar document.

(e) JJI shall by the first business day of each calendar month provide purchase orders to Medscand for JJI's Product requirements for that calendar month which is two months after the delivery date of such purchase order. Medscand shall be obligated to supply such Products as requested by JJI to the extent the purchase orders do not exceed by an amount greater than 50% from the forecasts provided pursuant to Section 4.9. JJI shall at all times be obliged to purchase the quantity of the Products requested in such purchase orders. Medscand shall at all times be obliged to supply that quantity of Products ordered pursuant to this Agreement.

4.4 **Payment for Product.** JJI will make payment upon any

ordered Products within thirty (30) days of the relevant invoice date of such Products provided such invoice was delivered to JJI within two (2) business days of such invoice date.

4.5 **JJI Supply of Prolene® Mesh and Sterilization Services.**

(a) JJI shall provide Medscand at no charge with such reasonable quantities of Prolene® mesh as shall be required for manufacture of the Products. Medscand shall provide JJI with no less than sixty (60) days prior written notice of any requirements for such mesh. Such mesh shall be provided F.O.B. JJI's designated facility in France. Medscand shall only use such mesh for purposes of manufacturing the Product pursuant to this Agreement.

(b) JJI shall also provide at no charge such sterilization services as are necessary for the finished Products, such sterilization services to be provided in accordance with JJI's normal and customary procedures. The parties shall negotiate in good faith such steps as shall be reasonably necessary in order for JJI to undertake such services.

4.6 **Initial Purchase Order.** JJI shall, within thirty (30) days after receipt by JJI of a written copy of the Product's CE Certification in the EEA, place a binding purchase order for no less than 3000 Needles and 100 Handles. Such binding purchase order shall be made at a special single order price of US$150 per set of Needles and US$500 per Handle.

4.7 **Trademarks and Packaging.**

(a) JJI shall provide to Medscand in writing the packaging requirements for the Products, which requirements, when determined, shall become part of the Specifications for each particular Product. JJI and Medscand shall also cooperate with each other in developing the labelling requirements for the Products which, when determined, shall become part of the Specifications for each particular Product. All such packaging and labelling requirements shall be specified within a reasonable period of time prior to the first shipment of each Product in order to allow Medscand to be able to satisfy JJI's requirements. In addition, from time to time, JJI may submit changes to such packaging and labelling specifications should JJI determine such changes are necessary or desirable. The party responsible for incurring the costs, if any, for such changes will be discussed in good faith between JJI and Medscand.

(b) Medscand acknowledges that JJI is the exclusive owner of and has all rights to the trademarks, copyrights, plans,

ideas, names, slogans, artwork and all other intellectual property that appear on or are otherwise used by JJI in connection with the Products. JJI acknowledges that such ownership rights do not extend to Medscand's proprietary formulae or other proprietary information. All trademarks to be used by JJI and/or its Affiliates in connection with the Products shall be chosen by JJI and/or its Affiliates in their sole discretion.

(c) JJI shall have the option, but not the obligation, to use the names "Ulmsten" and/or "Medscand" in connection with the marketing, distribution, promotion, advertising and sale of the Product. Any such use shall be without charge or cost to JJI, and shall be made pursuant to that certain trademark license agreement attached as Exhibit G to this Agreement.

4.8 **Product Defects and Warranties**.

(a) Delivery of any Product by Medscand to JJI shall constitute a certification by Medscand that the Product conforms to the Specifications. After delivery of a shipment of any Product to JJI, JJI shall have thirty (30) days to examine the Product to determine if they conform to the Specifications and, on the basis of such examination, to accept or reject such shipment. Any claims for failure to so conform ("Claims") shall be made by JJI in writing to Medscand, indicating the nonconforming characteristics of the Product.

(b) If Medscand agrees with such Claim, then as promptly as possible after the submission of a Claim by JJI, Medscand shall, at JJI's option, provide JJI (i) with a credit against future billings equal to the full amount paid by JJI for such Products or (ii) replacement Products. Medscand shall pay for all shipping costs of returning or destroying Products that are the subject of such accepted Claims. Medscand shall bear the risk of loss for such Products, beginning at such time as they are taken at JJI's premises for return delivery.

(c) If Medscand does not agree with such Claim, then the parties agree to submit the Products in question to an independent party which has the capability of testing the Products to determine whether or not it complies with the Specifications. In the event the parties cannot agree upon such independent party, or in the event it is not possible to acquire the services of such an independent party, then such dispute shall be resolved pursuant to Section 6.13.

(d) Medscand warrants all Products to be free from defects in workmanship or material (other than those defects arising solely from any materials or services provided by JJI) for a period of three (3) years from the date of shipment to the

ultimate end-user or until the expiration date printed on the packaging material, whichever is shortest. If any Product does not conform to the above warranty, Medscand shall be obligated to repair or replace such Product at its own expense, and ship such repaired or replacement Product back to either JJI or the applicable customer at its own expense. All defective Products returned to JJI by customers which are covered by the foregoing warranty shall be shipped to Medscand at its expense for such repair or replacement

4.9 **Forecasts**. During the term of this Agreement, JJI shall provide to Medscand no later than the first day of each calendar quarter a non-binding good faith estimate by month of JJI's requirements for the Products for the next twelve (12) calendar months. In addition, JJI shall provide an initial forecast no later than three (3) months prior to the estimated first commercial sale of the Product.

4.10 **Short-Shipments**. JJI shall notify Medscand of any short-shipment claims within thirty (30) days of receipt of a shipment of Products.

4.11 **Inspection of Product Facility**. Upon commencement of commercial production of the Products by Medscand, JJI shall have the right, upon reasonable advance notice and during regular business hours, to inspect and audit the facilities being used by Medscand for production of the Products to assure compliance by Medscand with applicable rules and regulations, FDA Good Manufacturing Practices, the CE Mark procedures, JJI quality control procedures, and with the other provisions of this Agreement. Such inspection and audit shall be conducted in a manner so as to minimize disruption of Medscand's business operations and shall not be conducted more than once per every two calendar quarters during the first two years after the first commercial sale of any Product and, thereafter, not more than once per every calendar year. Medscand shall within ninety (90) days remedy any deficiencies which may be noted in any such audit. In the event that Medscand does not remedy, or is incapable or remedying, any of such deficiencies within such ninety (90) day period, then JJI shall be entitled to terminate the supply provisions of Section 4 of this Agreement upon written notice to Medscand, in which event (a) JJI shall be entitled to manufacture or have manufactured the Products and (b) Medscand shall provide such assistance and other information as shall be necessary in order for JJI to manufacture or have manufactured the Products. Medscand acknowledges that the provisions of this Section granting JJI certain audit rights shall in no way relieve Medscand of any of its obligations under this Agreement, nor shall such provisions require JJI to conduct any such audits. If JJI determines to take over manufacturing of the Product pursuant

to the provision of this Agreement, JJI shall pay to Medscand the amount of US$45 per unit of Product which is so manufactured and sold by JJI.

4.12 **Adverse Events; FDA Audits.**

(a) The parties recognize that the holder of all regulatory filings and registrations may be required to submit information and file reports to various governmental agencies on Products under clinical investigation, Products proposed for marketing, or marketed Products. Consequently, each party agrees to provide to the other within three (3) days of the initial receipt of a report of any adverse experience with a Product that is serious. Serious adverse experiences mean any experience that suggests a significant hazard, contraindication, side effect or precaution, or any experience that is fatal or life threatening, is permanently disabling, or requires or prolongs inpatient hospitalization.

(b) Medscand shall promptly provide to JJI copies of any FDA or Regulatory Agency inspection reports it receives from such agencies.

4.13 **Recalls.**

(a) In the event any governmental agency having applicable jurisdiction shall order any corrective action with respect to a Product supplied hereunder (including any recall of any product containing a Product), customer notice, restriction, change, corrective action or market action or any Product change, and the cause or basis of such corrective action is attributable to a breach by Medscand of any of its warranties, guarantees, representations, obligations or covenants contained herein, then Medscand shall be liable, and shall reimburse JJI for the reasonable costs of such action, including the cost of any Product affected thereby whether or not such particular Product shall be established to be in breach of any warranty by Medscand hereunder.

(b) In the event that JJI determines to undertake any recall of any Product supplied hereunder (including any recall of any product containing a Product), customer notice, restriction, change, corrective action or market action or any Product change, and the cause of such corrective action is due to a breach by Medscand of any of its warranties, representations, obligations or covenants contained herein, then Medscand shall be liable, and shall reimburse JJI for the reasonable costs of such action, including the cost of any Product affected thereby whether or not such particular Product shall be established to be in breach of any warranty by Medscand hereunder.

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SECTION 5.

GENERALLY APPLICABLE TERMS

5.1 **Representations and Warranties.**

(a) Medscand represents and warrants to JJI that:

(1) the Products will be manufactured in accordance with the Specifications for such Product;

(2) the Product shall be safe and effective for the uses and indications therefor approved pursuant to the relevant Regulatory Approval;

(3) the Products shall be free from defects in materials, design or workmanship (such representation not extending to any materials or processing activities specifically provided or undertaken by JJI);

(4) the Products are being sold to JJI free and clear of all liens, claims and encumbrances of any nature;

(5) the Products, to the best of Medscand's knowledge, do not violate any patents, patent rights, patent applications, inventions, copyrights, confidential information, trade secrets, proprietary rights or processes of any other person;

(6) there are no pending or threatened suits, claims, or actions of any type whatsoever with respect to the Products;

(7) all Patents necessary or related to the manufacture, sale or distribution of the Products are listed on Exhibit B;

(8) all necessary corporate and other authorizations, consents and approvals which are necessary or required for the entering into of this Agreement have been duly obtained; and

(9) the entering into of this Agreement by Medscand will not (i) violate any provision of law, statute, rule or regulation or any

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ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body or (ii) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute a default (or give rise to any right of termination or cancellation) under, or result in the creation of any lien, security interest, charge or encumbrance upon any of the properties or assets of Medscand, under its organizational documents, as amended to date, or any material note, indenture, mortgage, lease, agreement, contract, purchase order or other instrument, document or agreement to which Medscand is a party or by which it or any of its properties or assets is bound or affected.

(b) JJI represents and warrants to Medscand that:

(1) the Prolene mesh provided pursuant to this Agreement shall be free from defects in materials, design or workmanship;

(2) all necessary corporate and other authorizations, consents and approvals which are necessary or required for the entering into of this Agreement have been duly obtained;

(3) to the extent required by applicable law, the sterilization equipment, methods and procedures will be validated and approved by relevant authorities; and

(4) the entering into of this Agreement by JJI will not (i) violate any provision of law, statute, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body or (ii) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute a default (or give raise to any right of termination or cancellation) under, or result in the creation of any lien, security interest, charge or encumbrance upon any of the properties or assets of JJI under its organizational documents, as amended to date, or any material note, indenture, mortgage,

lease, agreement, contract, purchase order or other instrument, document or agreement in which JJI is a party or by which it or any of its properties or assets is bound or affected.

5.2 **Indemnification**. In order to distribute among themselves the responsibility for claims arising out of this Agreement, and except as otherwise specifically provided for herein, the parties agree as follows:

i. Medscand agrees to defend and indemnify and hold JJI harmless against any and all claims, suits, proceedings, expenses, recoveries and damages (including, but not limited to, any expenses incurred in connection with any Product recall), including court costs and reasonable attorneys fees and expenses, arising out of, based on, or caused by (A) product liability claims related to alleged defects in materials, design or workmanship of the Products (including, but not limited to, the packaging of them by Medscand or its suppliers) or the failure of the Products to meet the Specifications, or (B) the breach by Medscand of any representation or warranty contained in this Agreement, in each case except to the extent that such arise from or are aggravated by acts of or failure to act by JJI. JJI will promptly notify Medscand of any such claim or demand which comes to its attention.

ii. JJI agrees to defend and indemnify and hold Medscand harmless against any and all claims, suits, proceedings, expenses, recoveries, and damages including court costs and reasonable attorneys fees and expenses, in connection with any of the Products sold by JJI arising out of, based on, or caused by (A) statements, whether written or oral, made or alleged to be made by JJI or its agents on the packaging or labelling of any of the Products and/or Products, or in the advertising, publicity, promotion, or sale of any of the Products, or (B) JJI's storage, sale, shipment, promotion or distribution of the Products, or (C) the breach by JJI of any representation or warranty contained in this Agreement, except to the extent that such arise from or are aggravated by acts of or failure to act by Medscand. Medscand will promptly notify JJI of any such claim or demand which comes to its attention.

5.3 **Other Responsibilities of Medscand**. During the term of this Agreement, Medscand shall:

i. Refer to JJI all customers' inquiries and correspondence which it receives relating to the sale of the Products, as

well as all correspondence or communications it receives with respect to any malfunction or failure of any Product;

ii. Make available to JJI such information and knowledge in Medscand's possession concerning the Products, their qualities and uses, as will aid JJI in improving the sales of Products;

iii. Maintain at all times manufacturing capacity and capabilities which shall allow it to satisfy the provisions of this Agreement and timely supply the Products to JJI as contemplated under this Agreement;

iv. Adhere to all law, rules and regulations applicable to the manufacture and supply of the Products under this Agreement.

5.4 **Insurance**. Medscand agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated hereby which policies shall provide for the type of insurance and amount of coverage described in Exhibit E. Upon JJI's request, Medscand shall provide to JJI a certificate of coverage or other written evidence reasonably satisfactory to JJI of such insurance coverage.

5.5 **Term**.

(a) This Agreement shall remain in effect until JJI provides at least one hundred and eighty (180) days' termination notice thereof; provided, however, that, unless terminated earlier by JJI in accordance with the terms of this Agreement, solely for purposes of that part of the Territory covered by the EEA, the exclusive Technology license granted pursuant to Section 3.1 shall remain exclusive only for ten (10) years with respect to Know-How and for the life of any Patents issued in such EEA country with respect to such Patent.

(b) Notwithstanding the foregoing Section 5.5(a), JJI may terminate this Agreement upon written notice to Medscand:

(1) if CE Marking certification for the Product is not obtained in within one hundred and eighty (180) days from the date of this Agreement (assuming any such delay shall not have resulted from any wrongful act of JJI under this Agreement); or

(2) at any time upon one hundred and eighty (180) days prior written notice by JJI to Medscand.

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(c) Notwithstanding the foregoing Section 5.5(a), if JJI has not purchased from Medscand in 1999 at least 13,500 units of Product (provided that Medscand has obtained CE Mark certification for the Product within 180 days of the date of this Agreement and provided that all such Product comply with the other provisions of this Agreement), then Medscand may terminate this Agreement upon written notice to JJI upon one hundred and eighty (180) days prior written notice thereof and payment to JJI of US$800,000.

(d) Medscand expressly acknowledges that the termination provisions contained in this Section are reasonable, considering the intended nature and scope of this Agreement, and considering the investments and undertakings required on the part of JJI in connection herewith.

5.6 **Events of Default**.

(a) The occurrence of any one or more of the following acts, events or occurrences shall constitute an "Event of Default" under this Agreement:

i. either party becomes the subject of a Bankruptcy Event; or

ii. either party breaches any material provision of this Agreement and fails to remedy such default within thirty (30) days after receipt of notice thereof; provided, however, that in the event of such a breach which cannot be remedied within such thirty (30) day period (other than a failure to supply Products to JJI pursuant to this Agreement), so long as the breaching party is diligently attempting to remedy such breach, an Event of Default shall not have occurred until three (3) months after notice of such breach (unless such breach is cured during such period).

(b) An Event of Default by Medscand shall also have occurred if a Change in Control of Medscand shall occur after the date of this Agreement and such Change in Control (i) involves a Competitor (as defined below) of JJI or any of its Affiliates, (ii) involves any entity which has had documented Good Manufacturing Practice problems with the U.S. FDA or any other regulatory authority, or (iii) involves a party which does not have the financial, production or other resources necessary for it to meet the obligations under this Agreement. For purposes of

this paragraph, the term "Competitor" shall mean any company or entity which is involved in the wound closure and/or suture and/or urinary incontinence business.

5.7 **Certain Rights After an Event of Default.** In addition to those rights which may be available at law or equity, the following additional rights shall be available to the non-defaulting party upon the occurrence of an Event of Default under this Agreement:

(i) If Medscand is the non-defaulting party, Medscand may terminate this Agreement upon written notice thereof to JJI. Upon termination of this Agreement by Medscand, JJI shall have one hundred eighty (180) days in which to sell out its stock of any Products it possesses or has committed to purchase under this Agreement; provided, however, that it is understood that JJI's ability to sell out such stock shall not be deemed to mean that this Agreement remains in effect in any manner.

(ii) If JJI is the non-defaulting party, JJI may, in its discretion, either (i) terminate this Agreement in its entirety or (ii) terminate only the provisions of Section 4 of this Agreement, in which event (a) JJI shall be entitled to manufacture or have manufactured the Products and (b) Medscand shall provide such assistance and other information as shall be necessary in order for JJI to manufacture or have manufactured the Products.

SECTION 6.

MISCELLANEOUS

6.1 **Confidentiality; Press Releases.**

(a) JJI and Medscand will be exchanging information relating to the Products at the inception of and from time to time during the term of this Agreement. Any such information which is considered by the disclosing party to be confidential will be identified in writing as confidential information or, if disclosed orally or in another non-written manner, shall be confirmed in writing as being confidential promptly after the disclosure thereof. The party receiving such information will maintain the information in confidence using the same standard of care it uses to maintain its own information in confidence. Such obligation of confidentiality shall not apply to information which (i) is known to the receiving party prior to the disclosure, (ii) is publicly known as of the date of the disclosure, (iii) becomes publicly known after the date of disclosure through no fault of the receiving party, (iv) is received from a third party who has no obligation of

confidentiality to the disclosing party or (v) is developed independently by the receiving party. Such obligation of confidentiality shall continue for a period of five (5) years from the date of disclosure of the confidential information.

(b) Notwithstanding the foregoing Section 6.1(a), JJI shall be permitted to disclose to its wholesalers and other direct customers such confidential information relating to the Products as JJI shall reasonably determine to be necessary in order to effectively market and distribute the Products, provided that such entities undertake the same confidentiality obligation as JJI has with respect to Medscand's confidential information.

(c) Neither party will originate any publicity, news release, or other public announcement, written or oral, whether to the public press or otherwise, relating to any amendment hereto or to performance hereunder or the existence of an arrangement between the parties, without the prior written approval of the other party.

(d) Neither party shall use the name of the other for advertising or promotional claims without the prior written consent of the other party.

6.2 **Survival**. Those provisions of this Agreement dealing with rights and obligations upon and/or after termination of this Agreement shall survive termination of this Agreement to the extent necessary to give effect to such provisions.

6.3 **Penalties**. If either party terminates this Agreement in accordance with the terms herein, the terminating party shall owe no penalty or indemnity to the terminated party on account of such termination.

6.4 **Independent Contractor**. Medscand is an independent contractor and shall have no authority to obligate JJI in any respect nor hold itself out as having any such authority. All personnel of Medscand shall be solely employees of Medscand and shall not represent themselves as employees of JJI.

6.5 **Binding Effect; Benefits; Assignment**.

(a) This Agreement shall enure to the benefit of and be binding upon the parties hereto and their respective permitted successors and assigns. Nothing contained herein shall give to any other person any benefit or any legal or equitable right, remedy or claim. Anything contained herein to the contrary notwithstanding, Medscand acknowledges that the rights and obligations under this Agreement of JJI may, from time to time, be exercised or performed, as the case may be, in whole or in

part by Affiliates of JJI.

(b) Anything contained herein to the contrary notwithstanding, this Agreement shall not be assignable by Medscand without the prior written consent of JJI, such consent not to be unreasonably withheld; provided, however, that if such assignment involves any entity of the type referenced in Section 5.6(b), then JJI's refusal of consent to such an assignment shall be deemed to have been reasonable.

(c) JJI shall be permitted to assign all or part of this Agreement to any Affiliate of JJI upon written notice to Medscand, provided that the assignee agrees in writing to assume the benefits and obligations of this Agreement. JJI shall also be permitted to assign this Agreement to any non-Affiliate of JJI upon the prior written consent of Medscand, such consent not to be unreasonably withheld.

6.6 **Entire Agreement; Amendments**. This Agreement and the other writings referred to herein or delivered pursuant hereto which form a part hereof contain the entire understanding of the parties with respect to its subject matter. This Agreement may be amended only by a written instrument duly executed by the parties hereto. To the extent of any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement shall govern.

6.7 **Remedies**. Unless otherwise expressly provided, all remedies hereunder (including, but not limited to, those remedies provided for in Section 5.7 hereof), are cumulative, are in addition to any other remedies provided for by law and may, to the extent permitted by law, be exercised concurrently or separately, and the exercise of any one remedy shall not be deemed to be an election of such remedy or to preclude the exercise of any other remedy.

6.8 **Severability**. In the event that any provision of this Agreement would be held in any jurisdiction to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as not to be invalid, prohibited or unenforceable in such jurisdiction, it shall, as to such jurisdiction, be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.

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6.9 **Force Majeure**.

(a) The obligations of Medscand and JJI hereunder shall be subject to any delays or non-performance caused by acts of God, earthquakes, fires, floods, explosion, sabotage, riot, accidents; orders of, or failure to issue all necessary permits or licenses by, regulatory, governmental, or military authorities; strikes, lockouts or labor trouble; perils of the sea; or any other similar cause beyond the reasonable control of either party. The party which is not performing its obligations under this Agreement as a result of an event of force majeure shall use diligent efforts to resume compliance with this Agreement as soon as possible. Should the event of force majeure continue unabated for a period of thirty (30) days or more, the parties shall enter into good faith discussions with a view to alleviating its affects or to agreeing upon such alternative arrangements as may be fair and reasonable having regard to the circumstances prevailing at that time.

(b) In the event that such alternative arrangements cannot be agreed upon within thirty (30) days after the expiration of such initial thirty (30) day period, and in the event that such force majeure results in an interruption in supply of a Product or Products in accordance with the terms of this Agreement, JJI shall have the right and option, upon written notice to Medscand (the "Force Majeure Notice"), to either manufacture itself the Products which are the subject of such force majeure event, or to have a third party so manufacture such Products. The Force Majeure Notice shall specify the Products which are the subject thereof. Upon delivery of the Force Majeure Notice to Medscand, (i) JJI shall be entitled to manufacture the Products itself, (ii) the provisions of Section 4 shall no longer apply with respect to such Products and (iii) Medscand shall provide such assistance and other information as shall be necessary in order for JJI to manufacture or have manufactured the Products. Upon such manufacture by JJI, JJI shall pay to Medscand an amount of US$45 per unit of Product sold by JJI which it has manufactured pursuant to this provision.

(c) In the event that such alternative arrangements cannot be agreed upon with thirty (30) days after occurrence of the event of force majeure, and in the event that such force majeure event does not result in an interruption of supply to JJI or its Affiliates of the Products in accordance with the terms of this Agreement, then the non-performing party shall continue to diligently attempt to alleviate such event of force majeure until it is removed or eliminated.

6.10 **Notices**. All notices, claims, certificates, requests, demands and other communications hereunder shall be in

writing and shall be delivered personally or sent by facsimile transmission, air courier, or registered or certified mail, return receipt requested, addressed as follows:

if to **Medscand** to:

Medscand Medical A.B.
Stadiongatan 65
S 20074
Malmo, Sweden
Attention: Managing Director
Fax: 46-40-987-801; and

if to **JJI** to:

JOHNSON & JOHNSON INTERNATIONAL
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
Attention: Secretary
Fax: 1-908-524-2788;

with a copy to:

Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933 U.S.A.
Fax: 1-908-524-2788;

or to such other address as the party to whom notice is to be given may have furnished to the other parties in writing in accordance herewith. Any such communication shall be deemed to have been delivered (i) when delivered, if delivered personally, (ii) when sent (with confirmation received), if sent by facsimile transmission on a business day, (iii) on the first business day after dispatch (with confirmation received), if sent by facsimile transmission on a day other than a business day, (iv) on the third business day after dispatch, if sent by air courier, and (v) on the seventh business day after mailing, if sent by mail.

6.11 **Waivers**. It is further understood and agreed that no failure or delay by either party hereto in exercising any right, power or privilege under this Agreement shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise of any right, power or privilege hereunder.

6.12 **Counterparts**. This Agreement may be executed in any number of counterparts, and execution by each of the parties of any one of such counterparts will constitute due execution of

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this Agreement. Each such counterpart hereof shall be deemed to be an original instrument, and all such counterparts together shall constitute but one agreement.

6.13 **Headings**. The article and section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

6.14 **Governing Law; Dispute Resolution**.

(a) Excepting only actions and claims relating to actions commenced by a third party against Medscand or JJI (including, without limitation, actions for injuries caused by a Product, or in respect to a patent infringement claim), any controversy or claim arising out of or relating to this Agreement, or the parties' decision to enter into this Agreement, or the breach thereof, shall be settled by arbitration in accordance with the arbitration Rules of the Zurich Chamber of Commerce, and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

(b) The arbitration shall be held before a panel of three (3) arbitrators, one each being selected by Medscand and JJI, and the third being selected by such two arbitrators. Arbitration shall be in Zurich, Switzerland, and the arbitrators shall apply the substantive law of the U.K.

(c) It shall be the duty of the arbitrators to set dates for preparation and hearing of any dispute and to expedite the resolution of such dispute. The arbitrators shall permit and facilitate discovery, taking into account the needs of the parties and the desirability of making discovery expeditious and cost-effective. The arbitrators will set a discovery schedule with which the parties will comply and attend depositions if requested by either party. The arbitrators will entertain such presentation of sworn testimony or evidence, written briefs and/or oral argument as the parties may wish to present; however, no testimony or exhibits will be admissible unless the adverse party was afforded an opportunity to examine such witness and to inspect and copy such exhibits during the pre-hearing discovery phase. The arbitrators shall among his other powers and authorities, have the power and authority to award interim or preliminary relief.

(d) The arbitrators shall not award either parties punitive damages and the parties shall be deemed to have waived any right to such damages. A qualified court reporter will record and transcribe the proceedings. The decision of the arbitrators will be in writing and judgment upon the award by the

arbitrators may be entered into any court having jurisdiction thereof. Prompt handling and disposal of the issue is important. Accordingly, the arbitrators are instructed to assume adequate managerial initiative and control over discovery and other aspects of the proceeding to schedule discovery and other activities for substantially continuous work, thereby expediting the arbitration as much as is deemed reasonable to him, but in all events to effect a final award within 365 days of the arbitrators' selection or appointment and within 20 days of the close of evidence.

(e) The proceedings shall be confidential and the arbitrators shall issue appropriate protective orders to safeguard both parties' confidential information. The fees of the arbitrators shall be paid by the losing party which shall be designated by the arbitrators. If the arbitrators are unable to designate a losing party, they shall so state and the fees shall be split equally between the parties.

IN WITNESS WHEREOF, duly authorized representatives of the parties hereto have duly executed this Agreement as of the date first above written.

JOHNSON & JOHNSON INTERNATIONAL

By: Philip E. Lane
Name:
Title:

MEDSCAND MEDICAL A.B.

By: _____
Name: Nils Stormby
Title: Chairman

ACKNOWLEDGEMENT:

Medscand A.B. hereby consents and agrees to this Agreement, and agrees to take such actions as shall be necessary in order for Medscand Medical A.B. to comply with the terms of this Agreement including, but not limited to, the transfer and assignment to Medscand Medical A.B. of any Technology which is owned or controlled by Medscand A.B.

MEDSCAND A.B.

By: _____
Name: Nils Stormby
Title: Chairman

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EXHIBIT A

SPECIFICATIONS

Initial specifications are attached. Parties shall determine in good faith within ninety (90) days of the Agreement the definitive specifications

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EXHIBIT F

Professor Ulmsten Consulting Agreement

CONSULTING AND TECHNOLOGY AGREEMENT

CONSULTING AND TECHNOLOGY TRANSFER AGREEMENT made as of February , 1997, between JOHNSON & JOHNSON INTERNATIONAL ("COMPANY"), a corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933 USA, and Professor Ulf Ivar Ulmsten ("SUPPLIER"), an individual with an address of Ridvagen 18D, 182 35 Danderyd, Sweden.

W I T N E S S E T H:

WHEREAS, SUPPLIER has been involved in the development of those certain products ("Products") which are proposed to be sold by COMPANY pursuant to a License and Supply Agreement ("License Agreement") dated the date hereof between COMPANY and Medscand Medical A.B. ("Medscand"); and

WHEREAS, SUPPLIER is under no obligation to any third party (other than as may be contemplated by the License Agreement) that would interfere with its rendering to COMPANY the professional services contemplated hereby; and

WHEREAS, COMPANY has now and from time to time in the future may have the desire to engage SUPPLIER's professional services in connection with the License Agreement; and

WHEREAS, COMPANY and SUPPLIER want to set out the terms under which SUPPLIER will transfer to Medscand certain intellectual property which will be used in connection with the manufacture, marketing, sale and/or license of the Products; and

WHEREAS, SUPPLIER is uniquely qualified to provide the services set forth in Section 1 and related services and SUPPLIER desires to render professional services to COMPANY on a non-exclusive basis concerning such matters;

NOW THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, the parties hereto agree as follows:

1. **Definitions**. As used in this Agreement, the following terms shall have the following definitions:

(a) **"Affiliate"** shall mean, in relation to either party hereto, (a) any company or other entity in which the relevant party directly or indirectly holds more than 50% of the voting securities, (b) any company or other entity ("Holding Company") which holds directly or indirectly more than 50% of the voting securities of the relevant party, (c) any other company or other entity in which more than 50% of the voting securities is directly or indirectly held by any Holding Company of the relevant party or (d) any company or other entity in which the relevant party directly or indirectly holds less than 50% of the voting securities but has management control of such company or entity in that it has the ability to appoint and remove the majority of the directors of such company or entity.

(b) **"Intellectual Property"** shall mean, collectively, the Patents and the Know-How.

(c) **"Know-How"** shall mean all know-how owned, controlled or acquired by SUPPLIER or any of its Affiliates at any time prior to or during the term of this Agreement, including without limitation, processes, techniques, methods, products, software (including the source code related thereto), components, apparatuses, or chemical materials and other materials and compositions, which are related to the manufacture, development, use or sale of (i) any Product or (ii) any products which can be used for the surgical treatment of stress urinary incontinence.

(d) **"Patent(s)"** shall mean (i) all the patents and applications for patents, if any, that are identified in Schedule B, any foreign counterparts thereof, as well as all continuations, continuations-in-part, divisions and renewals thereof, all patents which may be granted thereon, and all reissues, reexaminations, extensions, patents of addition and patent of importation thereof, (ii) any SUPPLIER patent application related to or based on any Know-How that is developed during the term of this Agreement, and any division, continuation or continuation-in-part of any such application and any patent which shall issue based on such application, divisional, continuation or continuation-in-part, and any patent which is a reissue or extension thereof or a patent of addition to any such patent and (iii) any other patents or patent applications which are owned or controlled by SUPPLIER or his Affiliates and which may be necessary to make, have made, use, distribute or sell any of the Products.

2. **Services.** (a) This Agreement constitutes an offer by COMPANY to SUPPLIER and the acceptance thereof by SUPPLIER to perform the consulting services set forth herein. SUPPLIER represents and warrants that it is under no obligation to any third party (other than as may be contemplated by the License

Agreement) that would interfere with its rendering to COMPANY the services contemplated by this Agreement.

(b) COMPANY hereby offers to engage and SUPPLIER accepts engagement by COMPANY of SUPPLIER's professional services on a non-exclusive basis as follows:

> Assistance and advice in connection with the launching of the Products under the License Agreement, and in supporting COMPANY's customer training and salesforce training and support activities in connection with such Product. Such assistance by SUPPLIER shall not exceed two days per calendar month. SUPPLIER shall perform such activities and provide such assistance as shall be reasonably requested by COMPANY in connection with such training and support activities.

The parties agree that the focus and definition of the services to be provided under this Agreement may develop and change during the term of this Agreement and, if so, the parties by mutual agreement will redefine in writing such services as needed.

(c) In addition, SUPPLIER hereby agrees to allow COMPANY to use SUPPLIER's name in connection with the manufacture, sale, promotion or distribution of the Products, such use to be in accordance with such reasonable terms as the parties shall mutually determine.

3. **Intellectual Property Transfer.**

(a) SUPPLIER or his Affiliates owns or controls (either individually or in conjunction with Medscand or its Affiliates) the Intellectual Property. SUPPLIER agrees to convey, transfer and assign to Medscand, or to cause to be conveyed, transferred and assigned to Medscand, all rights, title and interest of SUPPLIER and his Affiliates in the Intellectual Property. Such Intellectual Property shall be conveyed free and clear of any liens, claims or encumbrances of any nature whatsoever, and shall be accomplished in form and substance reasonably satisfactory to COMPANY.

(b) Transfer of the Intellectual Property shall be accomplished no later than March 31, 1997. Upon completion of the transfer of the Intellectual Property in accordance with this Agreement, COMPANY shall promptly remit to SUPPLIER or his designated Affiliates the amount of US$600,000.

4. **Confidential Information; Rights to Inventions and Copyrights.** (a) Any information acquired by SUPPLIER from COMPANY concerning existing or contemplated machines, products,

processes, techniques, or know-how, or any proprietary or confidential information or data developed pursuant to the performance of the consulting services contemplated hereunder shall not be disclosed by SUPPLIER or its employees, representatives or agents to others or used for SUPPLIER's own benefit without the prior written consent of COMPANY. Notwithstanding the foregoing, information shall not be considered confidential, proprietary or sensitive only to the extent that such information (a) is already known to SUPPLIER and not subject to any confidentiality restrictions at the time it is obtained from COMPANY, (b) is or becomes publicly known through no wrongful act of SUPPLIER, or (c) is rightfully received by SUPPLIER from a third party without restriction on further disclosure. All materials supplied to SUPPLIER by COMPANY, and any copies thereof, shall be returned to COMPANY within thirty days after the completion of any work under the Agreement or within thirty days after COMPANY requests the return thereof.

(b) Any copyrightable work whether published or unpublished created by SUPPLIER directly as a result of or during the performance of services hereunder shall be considered a work made for hire, to the fullest extent permitted by law and all right, title and interest therein, including the worldwide copyrights, shall be the property of COMPANY as the employer and party specially commissioning said work. In the event that any said copyrightable work or portion thereof shall not be legally qualified as a work made for hire, or shall subsequently be so held to not be a work made for hire, SUPPLIER agrees to assign, and does hereby so assign to COMPANY, all right, title and interest in and to said work or portion thereof, including but not limited to the worldwide copyrights, extensions of such copyrights, and renewal copyrights therein, and further including all rights to reproduce the copyrighted work in copies or phonorecords, to prepare derivative works based on the copyrighted work, to distribute copies of the copyrighted work, to perform the copyrighted work publicly, to display the copyrighted work publicly, and to register the claim of copyright therein. SUPPLIER, without charge to COMPANY, shall duly execute, acknowledge, and deliver to COMPANY all such further papers, including assignments and applications for copyright registration or renewal, as may be necessary to enable COMPANY to publish or protect said words by copyright or otherwise in any and all countries and to vest title to said works in COMPANY, or its nominees, their successors or assigns, and shall render all such assistance as COMPANY may require in any proceeding or litigation involving the rights in said works.

(c) No party to this Agreement will originate any publicity, news release, technical article or other public announcement, written or oral, whether to the public press or

otherwise, relating to this Agreement or to performance hereunder or the existence of an arrangement between the parties without the prior written consent of the other party.

(d) On or prior to the date of this Agreement, SUPPLIER shall provide a duly executed copy of Schedule A to this Agreement.

5. **Term**. The term of this agreement shall be from the date hereof until the fifth anniversary hereof. COMPANY reserves the right to terminate, at any time, any services authorized by this Agreement. This Agreement shall also terminate automatically upon the termination of the License Agreement.

6. **No-Compete**. Without the prior written consent of COMPANY, during the term of this Agreement, including any renewals or extensions thereof, and for a period of six months thereafter, SUPPLIER agrees not to perform any services for any person or company involving the provision of consulting or training services, or the manufacture, sale, development or evaluation of any product, in each case which may relate to the field of surgical treatment of urinary stress incontinence. The foregoing no-compete obligations shall not restrict SUPPLIER from engaging in non-remunerated teaching and speaking activities in his role as a Professor.

7. **Independent Contractor**. It is expressly stipulated, agreed and understood between the parties that the relationship between SUPPLIER and COMPANY shall be that of independent contractor and not employer-employee or principal-agent. Neither party shall have the authority to legally bind the other in contract, debt or otherwise.

8. **Assignment; Etc.** This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective permitted successors and assigns. Nothing contained herein shall give to any other person any benefit or any legal or equitable right, remedy or claim. Anything contained herein to the contrary notwithstanding, this Agreement shall not be assignable by SUPPLIER without the prior written consent of COMPANY, which consent may be withheld in the sole discretion of COMPANY. COMPANY may, without the consent of SUPPLIER, sell, assign or otherwise transfer this Agreement and the rights, benefits and duties hereunder to any affiliate of COMPANY.

9. **Complete Agreement**. This Agreement and the other writings referred to herein or delivered pursuant hereto which form a part hereof contain the entire understanding of the parties with respect to its subject matter. There are no restrictions, promises, warranties, covenants or undertakings other than those

expressly set forth herein or therein. This Agreement supersedes all prior agreements and understandings among the parties with respect to its subject matter. This Agreement may be amended only by a written instrument duly executed by the parties hereto.

10. **Notices**. All notices, claims, certificates, requests, demands and other communications hereunder shall be in writing and shall be delivered personally or sent by facsimile transmission, air courier, or registered or certified mail, return receipt requested, addressed to the address set forth at the beginning of this Agreement, or to such other address as the party to whom notice is to be given may have furnished to the other parties in writing in accordance herewith. Any such communication shall be deemed to have been delivered (i) when delivered, if delivered personally, (ii) when sent (with confirmation received), if sent by facsimile transmission on a business day, (iii) on the first business day after dispatch (with confirmation received), if sent by facsimile transmission on a day other than a business day, (iv) the third business day after dispatch, if sent by air courier, and (v) the fifth business day after mailing, if sent by mail.

11. **Severability**. In the event that any provision of this Agreement would be held in any jurisdiction to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as not to be invalid, prohibited or unenforceable in such jurisdiction, it shall, as to such jurisdiction, be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.

12. **Dispute Resolution**. Any controversy or claim arising out of or relating to this Agreement, or the parties' decision to enter into this Agreement, or the breach thereof, shall be settled by arbitration in pursuant to the provisions of the License Agreement, which provisions are hereby incorporated into this Agreement in their entirety by reference.

13. **Waivers**. The waiver by any party of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

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14. **Counterparts**. This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

JOHNSON & JOHNSON INTERNATIONAL

By:_____
Name:
Title:

Professor Ulf Ivar Ulmsten

_____

ACKNOWLEDGED AND AGREED:

MEDSCAND MEDICAL A.B.

By:_____
Name:
Title:

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SCHEDULE A

ACKNOWLEDGMENT

The undersigned, acting as a Director of the University Hospital of Uppsala (which University Hospital is the employer of Professor Ulmsten), hereby acknowledges that the Hospital has no claims on the technologies described in the patents and patent applications listed in the attached Exhibit B. The University also acknowledges that Professor Ulmsten will be providing certain consulting services to Johnson & Johnson International in connection with such patents and technology.

UNIVERSITY HOSPITAL OF UPPSALA

By: _____
Name:
Title:
Date: February __, 1997

Schedule B

INTELLECTUAL PROPERTY

1. Swedish Patent No. 503271 " Instrumentarium for behandling av urininkontinens hos kvinnor samt satt for sadan behandling", filed August 30, 1994, Application No. 94 02872-7.

2. International Application No. PCT/SE95/00964 "Surgical Instrument for Treating Female Urinary Incontinence." Filed August 28, 1995, published as WO 96/06567.

3. Swedish Patent Application "Surgical Instrument for Treating Urinary Incontinence" No. 9503512-7.

4. International Patent Application No. PCT/SE96/01269 "Surgical Instrument for Treating Urinary Incontinence".

5. Patent Application in India (No. 30/3-200/DEL/96) and Russia (No. 30/1 2412-2412-214650/042).

6. Patent Application in Australia 9534024.

EXHIBIT G

TRADEMARK LICENSE AGREEMENT

LICENSE AGREEMENT entered into this _____ day of February, 1997, between JOHNSON & JOHNSON INTERNATIONAL, located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933 USA (hereinafter referred to as LICENSEE), and Medscand A.B., located at S-200 74 Malmo, Sweden (hereinafter referred to as LICENSOR), in accordance with the following recitals and clauses:

RECITALS

WHEREAS, the LICENSOR is the owner of the Medscand trademark in those countries identified on the attached Schedule A of this agreement (individually a "Trademark" and collectively, the "Trademarks");

WHEREAS, the LICENSEE may be engaging in the manufacture, marketing or sale of certain medical device products ("Products") which may use the Trademarks pursuant to that certain License and Supply Agreement ("Supply Agreement") between LICENSEE and Medscand Medical A. B. dated as of February __, 1997; and

WHEREAS, LICENSEE and its permitted assigns and affiliates may desire to use the Trademarks in connection with such manufacture, marketing or sale of the Products

NOW, THEREFORE, the parties hereto agree as follows:

1. The LICENSOR hereby grants unto the LICENSEE a license to use the Trademarks in connection with the manufacture, marketing or sale of the Products.

2. The LICENSEE agrees and undertakes to use the Trademarks only on Products which are manufactured in accordance with good manufacturing practices and in accordance with any applicable standards set out in the Supply Agreement.

3. The LICENSEE recognizes the ownership of and title to the Trademarks by the LICENSOR, and will not at any time do or suffer to be done any act or thing which will in any way impair the rights of the LICENSOR in and to the same.

4. The LICENSEE agrees to use the Trademarks in accordance with all applicable law.

5. This License shall terminate upon the termination or expiration of the Supply Agreement.

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6. LICENSOR agrees to indemnify defend and indemnify and hold LICENSEE harmless against any and all claims, suits, proceedings, expenses, recoveries and damages, including court costs and reasonable attorneys fees and expenses, arising out of, based on, or caused by the placement of any Trademark on any Product packaging or labelling in accordance with this license.

7. This License may be assigned in whole or in part to any Affiliate (as defined in the Supply Agreement) of LICENSEE, or to any of LICENSEE's permitted assigns under the Supply Agreement.

IN WITNESS WHEREOF, the parties have entered into this License Agreement as of the date first set out above.

LICENSEE	**LICENSOR**
JOHNSON & JOHNSON INTERNATIONAL	**MEDSCAND A.B.**
By: _____	By: _____
Title:	Title:

JOHNC\WPDOCS\MEDSCAND.1

SCHEDULE A

Trademarks Specifics

Country	Reg. No.
Sweden	230 148
Norway	88.0333
Denmark	5913/91
Benelux	397 275
Great Britain	1 236 781
Germany	1 085 874
USA	1 753 468
Japan	2180935

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SCHEDULE A

ACKNOWLEDGMENT

The undersigned, acting as a Director of the University Hospital of Uppsala (which University Hospital is the employer of Professor Ulmsten), hereby acknowledges that the Hospital has no claims on the technologies described in the patents and patent applications listed in the attached Exhibit B. The University also acknowledges that Professor Ulmsten will be providing certain consulting services to Johnson & Johnson International in connection with such patents and technology.

UNIVERSITY HOSPITAL OF UPPSALA

By: _____
Name:
Title:
Date: February 26, 1997

Schedule B

INTELLECTUAL PROPERTY

1. Swedish Patent No. 503271 " Instrumentarium for behandling av urininkontinens hos kvinnor samt satt for sadan behandling", filed August 30, 1994, Application No. 94 02872-7.

2. International Application No. PCT/SE95/00964 "Surgical Instrument for Treating Female Urinary Incontinence." Filed August 28, 1995, published as WO 96/06567.

3. Swedish Patent Application "Surgical Instrument for Treating Urinary Incontinence" No. 9503512-7.

4. International Patent Application No. PCT/SE96/01269 "Surgical Instrument for Treating Urinary Incontinence".

5. Patent Application in India (No. 30/3-200/DEL/96) and Russia (No. 30/1 2412-2412-214650/042).

6. Patent Application in Australia 9534024.

Exhibit B

PATENTS

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2. International Application No. PCT/SE95/00964 "Surgical Instrument for Treating Female Urinary Incontinence." Filed August 28, 1995, published as WO 96/06567.

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6. Patent Application in Australia 9534024.

EXHIBIT C

CLINICAL TRIALS
[See 12/23/96 Draft Attached]

DRAFT DECEMBER 23 , 1996
EXHIBIT C

CLINICAL TRIALS

The results of the clinical trials will be considered acceptable if, first, they do not differ significantly from the results published in the original article published in Int. Urogynecol J (1996) 7 : 81-86 by U. Ulmsten and al. with regards to ghe following items :

1. Safety

1.1. Per-operative complications

- Bleeding > 300 ml
- Bladder performation

1.2. Post-operative complications (1 year from operation)
- Infection and/or rejection of the material
- Defect healing
- Slight post-operative voiding problems
- Chronic voiding problems

2. Efficacy

2.1. Short term results (1 year from operation)
- Patients considered as cured (completely dry)
- Patients considered as significantly improved (occasional leak in severe stress situations)
- Patients considered as failed (no significant improvement)

Second, long term results (over 1 year from operation) do not show a deterioration rate significantly different from those of the standards sub-urethral slingplasties. It is assumed that from 12 to 60 months a small gradual decrease in efficacy of 5 % is normal.

Third, no significant number of unexpected (i.e. not addressed in the Original Article published in Int. Urogynecol J (1996) 7 : 81-86 by U. Ulmsten and al.) procedure-related (i.e. not addressed in the Review Article published in Int. Urogynecol J (1994) 5 : 228-239 bu G.M. Ghoniem and al.) complications appear at any time in the postoperative course.

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EXHIBIT D

INFLATION INDEX

Producer Price Index Export published monthly by Statistiska Central Byran (SCB) in Sweden (or any successor index in the event such index is no longer published).

EXHIBIT E

INSURANCE COVERAGE

At least US$5 million per occurrence and US$10 million in the aggregate general liability insurance with an insurance carrier which is well-recognized in the European Community.

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Editorial Manager(tm) for European Urology
Manuscript Draft

Manuscript Number: EURUROL-D-03-00754R1

Title: Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out

Article Type: Original Article

Section/Category:

Keywords: stress urinary incontinence; technique; transobturator; urethra; suspension

Corresponding Author: Jean de Leval, MD, PhD, University of Liege

First Author: Jean de Leval

Order of Authors: Jean de Leval

Abstract:

Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out

Jean de Leval, MD, PhD

Department of Urology, University Hospital of Liège, Liège, Belgium

Running head: Transobturator inside-out tension-free urethral suspension

Key words: stress urinary incontinence, technique, transobturator, urethra, suspension

Number of pages: 18 Number of tables: 0 Number of figures: 4

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Abstract

Objectives: To describe a new, simple surgical technique for the treatment of female stress urinary incontinence (SUI) and to evaluate its feasibility.

Methods: We have developed a novel surgical treatment of SUI, the transobturator inside-out tension-free urethral suspension, which uses specifically designed surgical tools, and in which a synthetic tape is passed from underneath the urethra, through the obturator foramens, towards the thigh folds, without entering the pelvic region at any time during the procedure. The tape is positioned without tension under the junction between mid and distal urethra.

Results: The procedure was carried out in 107 consecutive patients (mean age = 62 years) using the same operative protocol in all case subjects, independently of the patient's size and weight. Mean operative time was 14 min (range = 7 to 20) in case of isolated SUI treatment. No bladder or urethral injury and no vascular (hematoma or bleeding) or neurological complication were encountered.

Conclusions: The results of this study indicate that our novel transobturator inside-out surgical technique for treating SUI is feasible, accurate, and quick. This technique avoids damage to the urethra and bladder and, therefore, makes cystoscopy not necessary. Further prospective studies are currently ongoing to determine the efficacy of our new surgical approach for treating SUI.

Introduction

Understanding of the physiopathological concepts of female stress urinary incontinence (SUI) has consistently improved over the past decades and their application has lead to the development of numerous surgical techniques aimed at curing this disorder [1, 2]. Among these, retro-pubic tension-free vaginal tape (TVT) has probably been the most revolutionary [3-10]. It has been suggested that retro-pubic TVT may stabilize the mid-urethra at the time of an abdominal pressure increase without modifying cervico-urethral mobility [11-14].

The wide use of retro-pubic TVT has been associated with various peri- and post-operative complications, including bladder perforation, temporary or persistent retention, pain, urinary infection, and *de novo* instability [9]. Other rare but severe – and possibly underestimated - complications have been reported with this approach [5, 15, 16]. Indeed, the blind passage of the needle in the retro-pubic space can result in injuries to other organs than the bladder, in particular the urethra, vessels, nerves and bowel.

To avoid these complications, alternate approaches with a pre-pubic [17] or transobturator [18-20] passage of the tape have been developed and continence rates obtained with these routes have been roughly similar to those after the 'classic' retro-pubic TVT at least on the short term. In the transobturator technique described by Delorme and colleagues, the tape is inserted through the obturator foramens from outside to inside (*in extenso* from the thigh folds towards underneath the urethra) [18]. Even though the transobturator out-in TVT technique is claimed to be a safe procedure, it may occasion urethra and bladder injuries [21].

In this study, we describe a novel surgical technique that allows the passage of a tape through the obturator foramens, from inside to outside, with the use of newly designed specific surgical instruments. Results obtained in a series of 107 consecutive patients

indicate that this surgical procedure is feasible, accurate, quick, and simple. In addition, this technique avoids damage to the urethra and bladder and, for this reason, makes cystoscopy not necessary.

Material and Methods

Specifically designed surgical instruments.

Three specific surgical instruments were created for the procedure: "helical passers", plastic tubes and an introducer (Figure 1).

The *"helical passers"* are pairs of instruments, specific for the left and right sides. They are stainless steel instruments comprising a spirally shaped section and a handle. The spiral section comprises an open circular segment having a 3cm radius terminated by 2 linear segments. On a horizontal plane perpendicular to the handle's axis, the gap between the extremities of the spiral section is 2cm.

The element supported by the helical passer is a *polyethylene tube* with a sharp pointed distal end. It bears a lateral opening, which allows the insertion of the spiral segment of the helical passer into its lumen. The proximal end of the tube is opened and it can be attached intra-operatively to a non-absorbable synthetic tape. In every patient included in this study, a non-absorbable mono-filament polypropylene tape (Gynecare, Somerville, NJ, USA) was used.

The instrument called the *"introducer"* is a stainless steel device that comprises two segments: a proximal tubular hollow segment and a distal, semi-circular, 7cm-long gutter. The introducer acts as a shoe-horn to ease, without danger, the slipping in of the passer, introduced alongside the gutter, from the perineal space through the obturator foramen.

Surgical technique.

The surgical procedure is generally carried out under spinal anesthesia but may also be performed under general or local anesthesia.

Two grams of third-generation cephalosporin are administered intravenously at the time of anesthesia induction, followed by 1 gram repeated 8 and 16 hours after the procedure.

The patient is first placed in the gynecological position, legs on stirrups and thighs in hyperflexion. The patient's buttocks reach the edge of the table. The operative field is cleaned with a standard antiseptic agent and draped with multiple drapes rather than a single trousers-shaped drape, with care being taken to keep the groin folds in the operative field. Labia minor are suspended by fixation to the skin with nylon suture a few centimeters above the vulvar ostium, inside the thigh folds, in order to expose the vulvar vestibulum. A 16 Fr Foley catheter is inserted into the bladder.

The points where the needles will exit at the skin level are identified by tracing a horizontal line at the level of the urethral meatus. The exit points are located 2 centimeters above this line and 2 centimeters outside the thigh folds (Figure 2A). A 5-mm skin incision is made at each exit point. The anterior vaginal wall is suspended with two Allis clamps on either side of the midline, 1 cm proximally to the urethral meatus. A median sagittal incision of the vaginal wall is started at this level and is continued proximally (towards the vaginal pouches) over a 1-cm distance (Figure 2B). Both vaginal mucosal and sub-mucosal tissues are incised. Minimal para-urethral sub-vaginal dissection is then carried out laterally with the blade, over a few millimeters distance, on either side (Figure 2C). One Allis clamp grasps right minor and major labia while another Allis clamp holds the left margin of the sub-urethral vaginal incision, to clearly expose the most posterior aspect of the right vulvar vestibulum. Fine dissection scissors are introduced through the blade-initiated dissection path, and then further (Figure 3A), on a horizontal plane with a 45° angle relatively to the urethral sagittal plane, towards the upper part of ischio-pubic ramus (Figure 3B). It is important to correctly expose the vulvar vestibulum and to respect the specific direction of the dissection in order to avoid any perforation of the vaginal wall.

Once the upper part of the ischio-pubic ramus is reached -a bone contact is perceived-, the right obturator membrane is perforated with the tips of the scissors, which are then slightly opened. During the dissection, bleeding can occur but is never important and only occasionally requires a blood-aspirating device. The introducer is then pushed in the pre-formed dissection pathway until it reaches and perforates the obturator membrane. The open side of the introducer's gutter must be facing the operator (Figure 3C). The distal end of the tube is mounted onto the spiral segment of the needle and the assembled device is gently slipped along the gutter of the introducer so as to pass through the obturator foramen (Figure 4A). The introducer and Allis clamps are removed. At this step, the handle of the passer must be aligned in a parallel manner with the sagittal axis of the vulvar slit (Figure 4B). Then, thanks to a rotational movement of the passer (Figure 4C and 4D), the pointed tip of the tube appears at the previously incised skin exit points at the level of the thigh folds (Figure 4E). The tube is pulled from the supporting passer, which is removed by a backwards-rotational movement, until the first centimeters of the tape become externalized (Figure 4F).

The same technique is applied to the left side. It is important to take care not to twist the tape. When both tubes have been extracted through the skin incisions, the ends of the tape are cut. The tape is then aligned under the junction between the mid and distal urethra and the tension of the tape is adjusted by exerting a traction on its two ends and by interposing a pair of scissors between the tape and the urethra so as to leave a space avoiding any tension of the tape. The plastic sheaths are then removed simultaneously. An alternative procedure for correctly aligning the tape under the urethra is to grasp the tape at its middle with Babcock forceps so as to create a small, 5mm-long tape loop (Figure 5A). As described above, traction is exerted on the distal ends of the tape, which brings the Babcock forceps grasps in contact with the urethra. Plastic sheaths (Figure 5B) and then Babcock forceps are removed and a small sub-urethral space is thus created between the

tape and the ventral aspect of the mid-urethra. The tape ends are cut in the subcutaneous layer and the incisions are closed.

Results

A total of 107 patients were consecutively operated on using the transobturator inside-out surgical procedure between March 2002 and February 2003. Informed consent was obtained from all patients before the operation. Surgery was carried out under spinal, general, and local anesthesia in 82, 24, and 1 cases, respectively. Mean age of the patients was 62,0 ± 12,6 years (median = 62,2 years; range = 29-88) and mean parity was 2,5 ± 1,7 (median = 2,5; range = 0-9). Seventeen patients (15,9%) had been operated previously for incontinence and/or vaginal prolapse.

Among the 107 patients, 74 of these suffered from typical symptoms of SUI, documented by detailed history, physical examination, endoscopic assessment and urodynamic testing. Ulmsten's test was positive in every case. The remaining patients (n=33) had pelvic organ prolapse requiring surgical treatment. In these patients, the transobturator vaginal tape inside-out was carried out after prolapse surgical correction (during the same anesthesia) for treating associated SUI (n=15) or for prophylactically preventing secondary SUI (n=18).

The procedure was carried out independently of the patient's size and weight, in all case subjects. Each of the 214 needles was passed through the obturator foramens and exited at the skin level exactly where it had been marked and incised.

Mean operative time was 14 min (median = 13; range = 7 – 20) in case of isolated SUI treatment. Patients with transobturator inside-out operations only were hospitalized for a mean of 1,8 days (range 0,5-8 days).

No peri-operative complication was encountered. No injury to the urethra, bladder, nerves or bowel was noted. Significant (>100mL) intra-operative bleeding did not occur. In none of the cases was the vaginal wall perforated during the operation. No ecchymose or hematoma was noticed after the procedure.

All patients had a follow-up visit at one month after surgery, including detailed interview by the surgeon, clinical examination, urine analysis, and postvoid residual determination. During this short follow-up time, only few post-operative complications were observed. Minor vaginal erosion was noted in one patient. Three patients (2.8%) had complete retention: two of them had undergone associated prolapse surgical treatment. In these patients, a tape release procedure was carried out in the immediate post-operative period with local anesthetic injection and intravenous sedation as needed. No tape required to be sectioned. None of the patients who underwent a tape release procedure developed incontinence or fistula.

Twenty-seven patients (15.9%) complained directly after the procedure that they had moderate pain or discomfort in the thigh folds. This symptom usually abated within 2 days and was in all cases controlled by non-opioid analgesics. In 2 patients (1.9%), more severe pain persisted for one week and was associated with hip arthralgia, probably as a result of the gynecological position during the procedure. Pain was not reported by any of the patients one month after the operation.

Superficial vein thrombosis occurred in one patient at day 8 after surgery, with secondary development of an abscess that required drainage. Evolution of this patient was favorable. Despite the sepsis was not in contact with the operative field (the abscess developed approximately 10 centimeters below the skin exit point of the passer), further to this adverse event, care was taken to prophylactically administer powerful antibiotics in all patients undergoing the surgical treatment.

Discussion

The main goal of surgical treatment for SUI is to render patients completely continent without generating significant morbidity. Until the advent of retro-pubic TVT, Burch's colposuspension has been considered the gold standard surgical procedure for SUI.

Accumulating reports have indicated the efficacy of tension-free sub-urethral tapes, which are currently widely utilized [4-10]. The results of a prospective randomized multicenter trial comparing retro-pubic TVT with colposuspension have recently shown that continence rates were similar at six months of follow-up, with more operative complications for retro-pubic TVT and more frequent post-operative complications and longer recovery for colposuspension [22, 23]. Retro-pubic TVT procedure required much less operative time, had much shorter hospitalization time, with significantly less post-operative pain and faster return to normal daily activities than Burch's colposuspension [22, 23].

Nevertheless, retro-pubic TVT has not been free of complication, as indicated by Boustead [9] and Sanjurjo et al. [10] in recent reviews on retro-pubic TVT. Bladder perforation occurred in 0%-23% of the patients, *de novo* urgency in 2.5%-25%, retention in 1.5%-12.9%, and hematoma in 0.8%-3.3%. Severe complications such as vascular and bowel injuries, as well as deaths, have been reported [9].

The outside-in transobturator technique proposed by Delorme [18, 20] may present several advantages, amongst which the occurrence of immediate complications may be less frequent. In particular, the author stated that there might be no risk to damage the bladder or the urethra, or to cause *de novo* urgency [17]. The concept that there is no risk of bladder or urethral perforation with Delorme's technique is not shared by everyone. Such complications have indeed been recently reported in 3 patients [21]. We have also recently treated 3 patients who had undergone outside-in transobturator TVT in other institutions

and who had subsequently developed urethral fistula (de Leval J., unpublished observation). In addition, Delmas et al. [24] have performed dissection studies in cadavers and their results have indicated that the risk of nerve or vessel injury is nearly absent. However, they have concluded that a risk of vagina, bladder and urethra damage is present. For this reason, the authors have proposed that a large opening should be carried out at the level of the vaginal dissection and have advised to use the tip of the index to pick up the end of the 'tunnelisateur'.

We have recently performed anatomical studies using cadavers to identify the exact passage of the needles and tape with our transobturator inside-out procedure (manuscript in preparation). We observed that the pelvic region was completely outside of the dissection field. Indeed, the tubes were immediately passed in a virtual space located in the most anterior part of the ischio-rectal fossa. This triangular space was limited in its internal region by the external plane of the levator ani muscle. Its inferior limit corresponded to the median perineal aponeurosis and its external boundary was constituted by the internal obturator muscle. The terminal end of the pudendal nerve was located below the median perineal aponeurosis. These anatomical observations demonstrated that there is no danger to generate neurological complications.

The passage of the tapes with our procedure and surgical devices was extremely accurate, as testified by the systematic exit location of the tubes at the pre-defined skin exit points. Our passage was different from the one described by Delorme [18] and Delmas [19, 24], since our anatomical studies have revealed that the levator ani muscles and the pelvic fascia were not perforated at any time during the procedure. In addition, our transobturator passage was carried out largely above the pudendal nerve landmark. Therefore, we herein claim that cystoscopy is not necessary, provided that our procedure is performed according to the proposed guidelines. Mean operative time should be consequently reduced.

In this study, no hematoma was observed after the procedure. This may be partly explained by the minimally carried out dissection, which, in addition, may reduce the risk of tape migration. It is also noteworthy that our dissection is performed in a space that is devoid of large vascular structures. Our dissection was performed under sight control with large exposure of the vulvar vestibulum, thus reducing the risk of vaginal wall perforation.

On the physiopathologic level, high continence rates obtained with the transobturator, retro-pubic or pre-pubic tapes share a common denominator, which is the restoration of the fixed bearing point at the junction between the middle and the distal third of the posterior urethra. Our previous works have indeed identified a fixed point, which is a genuine pivot of rotation, from which two urethral segments – inferior and superior - can be distinguished [25]. The anatomical correspondence of this point of confluence is the median perineal aponeurosis [25-26]. We thus believe that the tape may restore this aponeurotic structure that is under-developed in women [26] and that may be altered by pregnancy/delivery.

This preliminary analysis mainly focused on the feasibility and immediate complication rates associated with our newly developed surgical procedure. Continence and *de novo* urgency rates are not provided due to the short follow up time (one month) in this study. In addition, the population of patients analyzed in this study was not homogenous since it incorporated patients with isolated SUI, patients with SUI and associated prolapse, and patients with prolapse without SUI. We are currently conducting other prospective studies in cohorts of patients with isolated SUI only to assess several important outcome variables, such as continence rates, the incidence of *de novo* urgency, and quality of life measures.

In conclusion, we propose the transobturator inside-out tension-free urethral suspension as a novel surgical procedure for treating SUI. This technique is feasible, accurate, quick, and simple, and avoids urethra, bladder, bowel, neurological and vascular

injuries. Further ongoing studies will help determine the efficacy of this new surgical technique.

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Figure legends

Figure 1. Specifically designed instruments for performing the transobturator inside-out tension-free urethral suspension: one pair of metallic "helical passers", plastic tubes, and an introducer.

Figure 2. A) Identification of the skin exit points of the needles by tracing a horizontal line at the level of the urethral meatus. The exit points (*asterisk*) are located 2 centimeters above this line and 2 centimeters outside the thigh folds. B) After suspension of the anterior vaginal wall with two Allis clamps on either side of the midline, a median sagittal incision of the vaginal wall is started 1cm proximally to the urethral meatus and is continued proximally over a 1-cm distance. C) While one Allis clamp grasps minor and major labia to expose the vulvar vestibulum, a minimal lateral para-urethral sub-vaginal dissection is carried out with a cold knife blade over a few millimeters distance.

Figure 3. A) Introduction of fine dissection scissors through the blade-initiated dissection path towards the upper part of ischio-pubic ramus, on a horizontal plane with a 45° angle relatively to the urethral sagittal plane, as indicated in B), to perforate the obturator membrane with the tip of the scissors. C) The introducer, with its open side facing the operator, is pushed in the pre-formed dissection pathway until it reaches and perforates the obturator membrane.

Figure 4. A) After the surgical device has been assembled by mounting the distal end of the tube onto the spiral segment of the "passer", it is slipped along the gutter of the introducer so as to pass through the obturator foramen. B) After removal of the introducer, the passer's handle is aligned in a parallel manner with the sagittal axis of the vulvar slit. C and D) The passer is rotated inside-out with the tip of the tube directed towards the skin exit points at the thigh folds. E) The pointed

tip of the tube appears at the previously incised skin exit points at the level of the thigh folds. F) The tube is pulled from the supporting passer, which is removed by a backwards-rotational movement.

Figure 5. A) Alignment and adjustment of the tension of the tape under the junction between the mid and distal urethra by grasping the tape at its middle with Babcock forceps so as to create a small tape loop. B) After traction has been exerted on the distal ends of the tape, which brings the Babcock forceps grasps in contact with the ventral aspect of the urethra, plastic sheaths are simultaneously removed at either end of the tape.

REVISION NOTES

To: Professor C.C. Schulman
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Reference: Manuscript EURUROL-D-03-00754 "Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out"

Dear Claude,

Please find our revised manuscript entitled "Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out" that we have modified according to your comments and to the reviewers' comments and adapted to the format of an article fitting in the section NEW SURGICAL TECHNIQUES.

We are delighted that our study was found acceptable for publication in European Urology, provided that adequate revisions are carried out. We are sincerely thankful to the reviewers whose remarks helped strengthen our manuscript. We are also grateful to you for your proposal of submitting the manuscript for the section NEW SURGICAL TECHNIQUES. We made all efforts to follow your recommendations for the revision of the manuscript. In particular, we have focused on the description and feasibility of the surgical technique and have withdrawn

the results on continence and de novo urgency rates at one month of follow up since this follow up time is very short.

Our specific responses to the reviewers' comments and consequent adaptations of the new form of the manuscript are as follow:

Reviewer #1 :

Comment #1: I enjoyed reading this article, which uses a slightly different approach to the surgical placement of the trans-obturator tape. This new technique offers an alternative to TVT. Whether it will be a replacement to or just an adjunct to TVT we will have to see. The only problem I have with the article is the description of the surgery. The passage of the needles is not too clear to me. It would be helpful if one or two more pictures could be included of the needle pass (perhaps with a surgical picture or two). Subject to these changes I feel the article is worthy of publications.

Reply form authors: We are delighted that this reviewer enjoyed reading our manuscript. We have now added 4 surgical photographs (Figures 4 C through F) to clarify and highlight the passage of the needle around the ischio-pubic ramus. In addition, we now provide surgical photographs of the different steps of procedure, concomitantly with the previous drawings. Modifications of the legends to the figures have been carried out accordingly.

Reviewer #2:

Comment #1: This is the first report of the use of a new technique that is of great intellectual interest. However, this reviewer has significant concerns with the publication of this report. The authors state their aim - to describe a novel mini-invasive surgical technique. They have accomplished this aim with an excellent technical description of a procedure.

Reply from authors: We very much appreciate that this reviewer found our new surgical technique of great intellectual interest. We are also delighted that this reviewer found that the

description of our novel surgical technique was accomplished with an excellent technical description of the procedure. Indeed, we believe that the simplicity and accuracy of the procedure makes it easy to describe.

Comment #2: However, the following problems are noted: Lack of human subjects consent for research. If this is in fact a new procedure, human subject consent should have been obtained for research. Without such consent, there is a major ethical breach.

Reply from authors: We can definitively reassure this reviewer. Indeed, informed consent was obtained from all patients participating in this study, before the operation. This information has now been added to the revised version of the manuscript at page 9, first paragraph, 2d line.

Comment #3: Unsubstantiated conclusions. The authors conclude that this procedure is reproducible and extremely safe. First, consider the claim for reproducible. This word means that it can be done the same way under the same situation. This does not apply to surgical technique since every patient is somewhat different, unless the same procedure is repeated in the same patient. Second is the claim for "extreme safety" - this claim must be withdrawn as it is totally unsubstantiated. No short-term (1 month) follow-up can demonstrate this level of safety. Moreover, a significant number of complications occurred even in this case series, despite the phrase (p. 8) that "no major peri- or post-operative complication was encountered". The authors report complete retention in 3%, 16% short-term pain that "usually abated" - details are necessary regarding patients whose pain did not abate. One abscess required drainage. Even if you just count these 4 (4/107) the rate is not insignificant at only 1 month.

Reply from authors: We agree with this reviewer that the word 'reproducible' may be misleading and, accordingly, have now withdrawn this word from the revised version of the manuscript. What we meant by 'highly reproducible' was that the passage of the needle was carried out on either side in all patients along a 'reproducible' or accurate path, since in all case subjects, the needle was always passed from underneath the urethra through the obturator foramen and always exited at the pre-defined skin exit points. We thus have changed 'reproducible' for 'accurate'.

We have also withdrawn the phrasing 'extremely safe'. By 'extremely safe' we signified that no complication was encountered during the operation. Three patients suffered from urinary

retention in the immediate post-operative period. This complication was treated successfully in all 3 cases. It is noteworthy that, in these 3 cases with urinary retention, we could have waited for spontaneous resolution of the problem (e.g. with a supra-pubic catheter). We took the option of an immediate tape release procedure for these patients. Obviously, this is debatable but explains why 3 patients have had an immediate tape release procedure.

Pain occurred in some patients but never required the administration of opioid analgesics. In the post-operative period, pain disappeared in most cases within 48 hours, and in all cases, had vanished at one month of follow-up.

As far as the patient with the thigh abscess is concerned, we do not know the exact patho-physiological mechanism that lead to the development of the abscess. The initial diagnosis was superficial thrombophlebitis. No sign of tape infection has ever been noted in this patient. The abscess was localized in the thigh more or less ten centimeters below the tape's skin exit point. Other possible explanations for the development of this abscess include: infected unrecognized hematoma, or infectious myositis. Whatever the origin of this abscess, since the systematic administration of large spectrum antibioprophylaxy to all patients (identical to the regular antibioprophylaxy given to patients undergoing the placement of prosthetic material), we have not observed anymore such adverse event. We have now carried out our transobturator inside-out procedure in more than 200 patients and, again, this infectious complication has not recurred.

Accordingly to this reviewer's comment, we have changed the sentence in page 9, fifth paragraph, 1th line to 'No peri-operative complication was encountered' (in the revised version). Also, the sentence in page 10, second paragraph, 3d line, was changed to 'During this short follow-up time, only few complications were observed' (modified version of the manuscript).

Comment #4: In the results section, the authors refer to the TVT operation. Presumably this is an error. Nevertheless, it is not clear why patients with "TVT" were hospitalized nearly two days for such a "mini-invasive" procedure. Gold-standard, autologous rectus fascia sling patients are hospitalized only one night.

Reply from authors: We apologize for this mistake. The term 'TVT' has been modified to 'transobturator inside-out'. Most patients were hospitalized for two days because most of the procedures had been carried out under spinal anesthesia for maximal comfort of the patients. Also, patients had been asked to enter the hospital the day before the operation. These reasons

thus explain the 2 days hospitalization for most patients. We have also demonstrated that the procedure can be performed under local anesthesia.

Comment #5: Poor description of patient population: Only 70% of patients "suffered from typical symptoms of SUI" while only half of the prolapse patients had such symptoms. Potential SUI is not defined. The methods of diagnosis and outcome measures are not defined. The description of vaginal support is not included. Sexual activity and pain are not discussed.

Reply from authors: As detailed in the manuscript, both patients with isolated SUI and patients with SUI associated with prolapse did participate in this study. In addition, transobturator inside-out procedure was also performed in some patients who were scheduled for pelvic prolapse repair and who had no pre-operative symptomatic SUI. In these patients, potential SUI was recorded on the basis of urodynamic studies that showed low urethral closure pressure. Transobturator inside-out procedure was carried out in these patients to prevent secondary SUI. Overall, 107 consecutive patients with various SUI and prolapse conditions were enrolled in this study. Whatever the pre-operative data, the main goal in this paper was to demonstrate the feasibility of our new surgical technique. As a matter of fact, to delineate the exact performance of our technique in terms of cure rates should require a homogenous population of patients (e.g. only patients with SUI and no sphincter deficiency/associated prolapse). We have already initiated further prospective studies that take into account this important issue rose by the reviewer.

Comment #6: Outcome measures are not described. Since the authors conclude that the operation is "effective", the outcome measures should be clarified. Who did the interview - in person or by phone - what was considered "SUI cure" - how this balanced if there were other symptoms, such as de novo urgency or pelvic organ prolapse following the procedure.

Reply from authors: Our primary outcome parameters in this study were mainly related to the feasibility of the technique, *in extenso* peri-operative and immediate post-operative complication rates, and surgical aspects of the procedure. All patients were seen at follow-up visit one month after the operation. Because of the heterogeneous population of patients and the short follow-up time in this study, we have decided to withdraw the results regarding continence and *de novo* urgency rates. As stated in reply to comment #5, we are now conducting further prospective studies devoted to the assessment of the technique's efficacy. These ongoing studies have

enrolled uniform cohorts of patients with isolated SUI only.

Comment #7: In summary, this reviewer believes that the technical aspects of this procedure do not warrant publication until there is an appropriate randomized control study with human subject consent. The fact that the procedure is intellectually interesting is not as important as how it helps patients. In this study, there is no evidence that this procedure is better than anything else that is provided to patients.

Reply from authors: We agree with this reviewer that to demonstrate that our procedure generates higher or at least equal continence rates than other surgical treatments for SUI requires prospective randomized trials. This concern was not the main purpose of our study. Such trials are currently being run in our Department. As stated above, informed consent was obtained from all patients in this study, before the operation.

Reviewer #3:

Comment #1: The author presents a new alternative to TVT, the in out transobturator tape (the way to cross the foramen is different from the Delorme's procedure, the passage of the tape is going from inside to outside). This procedure is original and seems attractive. Furthermore, the results show 88 % of success with a follow up of 1 month. The rate of voiding difficulties is about 2.8%, the rate of* de novo *urgency is 8.4%. There was 1 vaginal erosion, 1 abscess, no vascular, bladder and bowel injury. However the main critical points are the short follow up (1 month), the non-defined methodology (examination, QOL, post operative course) and a lot of questions without answer. Title: What is the goal of this manuscript: description of a new procedure, prospective or retrospective trial, short-term results?

Reply from authors: The goal of this study was to propose a new surgical technique for treating SUI and to evaluate its feasibility. Detailed analysis of the results pertaining to this technique in terms of continence rates, quality of life measures, and other variables is being currently carried out in another prospective study enrolling patients with isolated SUI only.

Comment #2: In the methods, the author has to define the methodology for the evaluation of the results.

Reply from authors: As requested by this reviewer, we have now modified some details about the methodology used for analysis of the results. Because i) the goal of this study is primarily to describe a new surgical technique and to determine its feasibility, ii) the follow-up time is short, and iii) the cohort of patients is heterogeneous in terms of pre-operative data (patients with isolated SUI *versus* patients with SUI and associated prolapse *versus* patients with prolapse and without SUI), we have decided to withdraw our very preliminary post-operative results regarding continence and *de novo* urgency rates.

Comment #3: Introduction. There is no relation between the surgical techniques and the references of De Lancey, Costa and Petros. The same remark about the references 6-13.

Reply from authors: We apologize for the confusion. References #2, #3 and #4 were indeed not related to surgical techniques but to hypothetical physiopathological concepts of TVT. For references #6 through #13, we believe that these references are related to the revolutionary aspect of TVT.

Comment #4: Methodology. The description of the procedure is correct, we suggest to the author to specify the paragraph surgical procedure independently of the method of evaluation.

Reply from authors: We do not understand this reviewer's comment since in our original version of the manuscript, the paragraphs 'Surgical technique' and 'Patients' are already specified independently.

Comment #5: A lot of questions about the methodology are missing: What is the definition of potential SUI? How many patients presented mixed urinary incontinence? The author presents a functional result with a follow up of 1 month, can the author explain if the functional result evolves according to time? It is necessary to define the method to draw the methodology of survey, what the author means by detailed interview, how was realized the clinical examination, how the author defines the voiding difficulties? There is a confusion between the material and the results, the paragraph about the patients characteristics has to stand in the results.

Reply from authors: Potential SUI was defined by pre-operative urodynamic testing showing low urethral closure pressure in a patient with pelvic organ prolapse and not complaining from symptoms of SUI. Some of the patients suffering from isolated SUI had associated urodynamic evidence of sphincter deficiency. Indeed, in this study assessing the feasibility of the surgical technique, and as already stated in the answer to comment #2, a heterogeneous cohort of patients was evaluated, precluding any detailed and in-depth analysis of continence rates for example (since results may be biased by the patients' selection). Accordingly to this reviewer's comment, the paragraph about the patients' characteristics has been moved to the Results section.

Comment #6: Results. We suggest to the author to draw a table with the characteristics of the patients, and describe for the population with previous procedures the variety of the procedures: in this population was there TVT? Line 5 the author confuse TVT and TOT. Where was the site of the abscess that required drainage? What was the Hb drop between the pre and post-operative course? What were the results of the patients with previous SUI procedures? What was the rate of UTI (Urinary tract infection)? Was there a difference between the objective and the subjective results according to the response to the "questionnaire"? How was define improvement and failure? What was the result according the mode of anesthesia, BMI, previous surgery, concomitant procedures?

Reply from authors: No patient in this study had had retro-pubic TVT prior to carrying out our transobturator inside-out procedure. We apologize for the confusion at page 8 between TVT and 'TOT'.

One patient developed an abscess in the inner thigh approximately 10 centimeters below the level of the exit of the tube at the level of the thigh fold. We do not know the exact physiopathological mechanism(s) that lead to the development of this abscess. The initial diagnosis was superficial thrombophlebitis. No sign of tape infection has ever been noted in this patient. Other possible explanations for the development of this abscess include: infected unrecognized hematoma, or infectious myositis. Since the systematic administration of large spectrum antibioprophylaxy to all patients (identical to the regular antibioprophylaxy given to patients undergoing the placement of prosthetic material), we have not observed anymore such adverse event. We have now carried out our transobturator inside-out procedure in more than 200 patients and, again, this infectious complication has not recurred.

We have not considered necessary to determine the drop in hemoglobin between before and after operation because in no case was encountered significant peri-operative bleeding or post-operative hematoma.

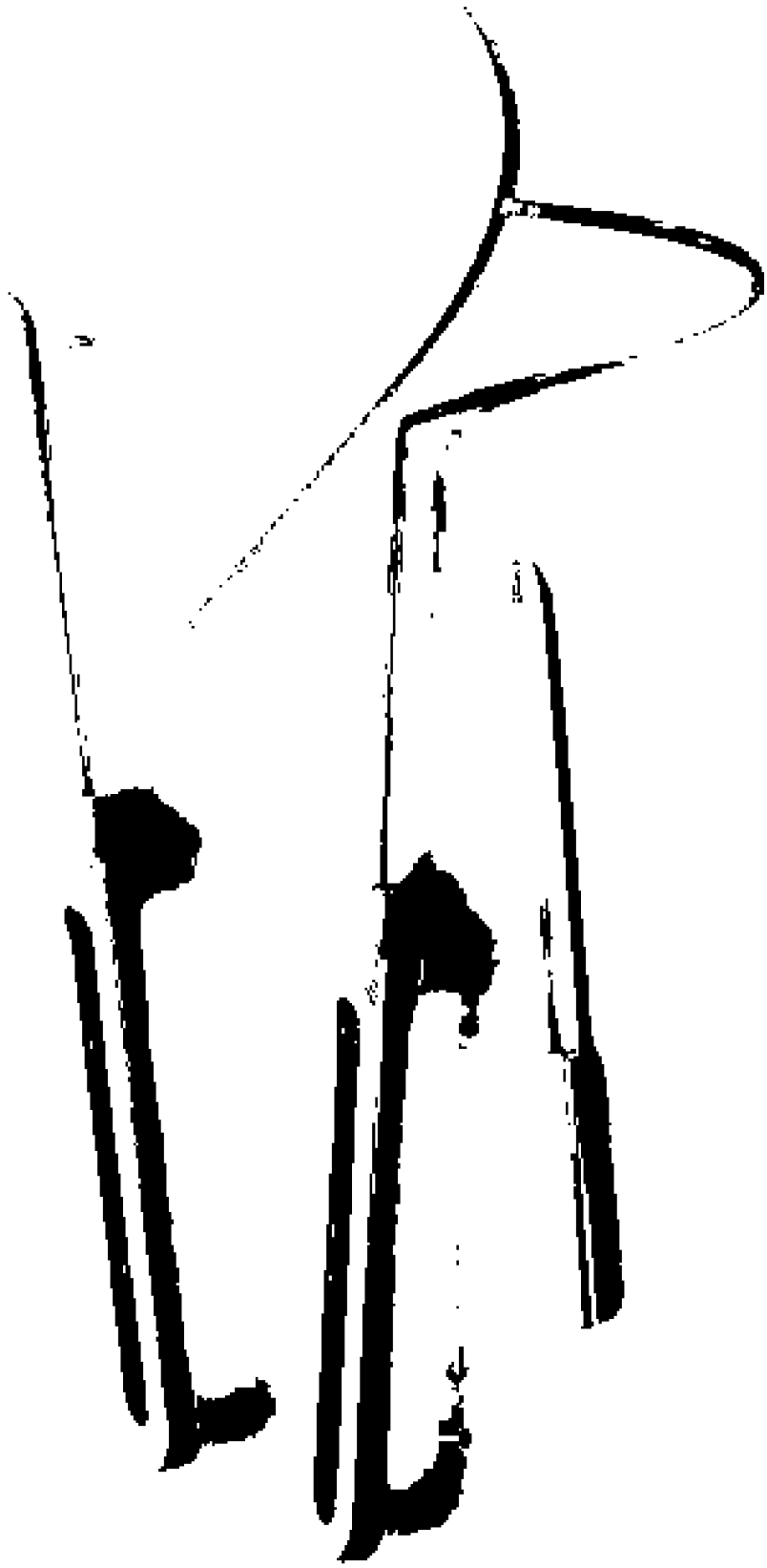
For reasons already detailed in answer to comment #, we have now decided to withdraw the data about continence and *de novo* urgency rates.

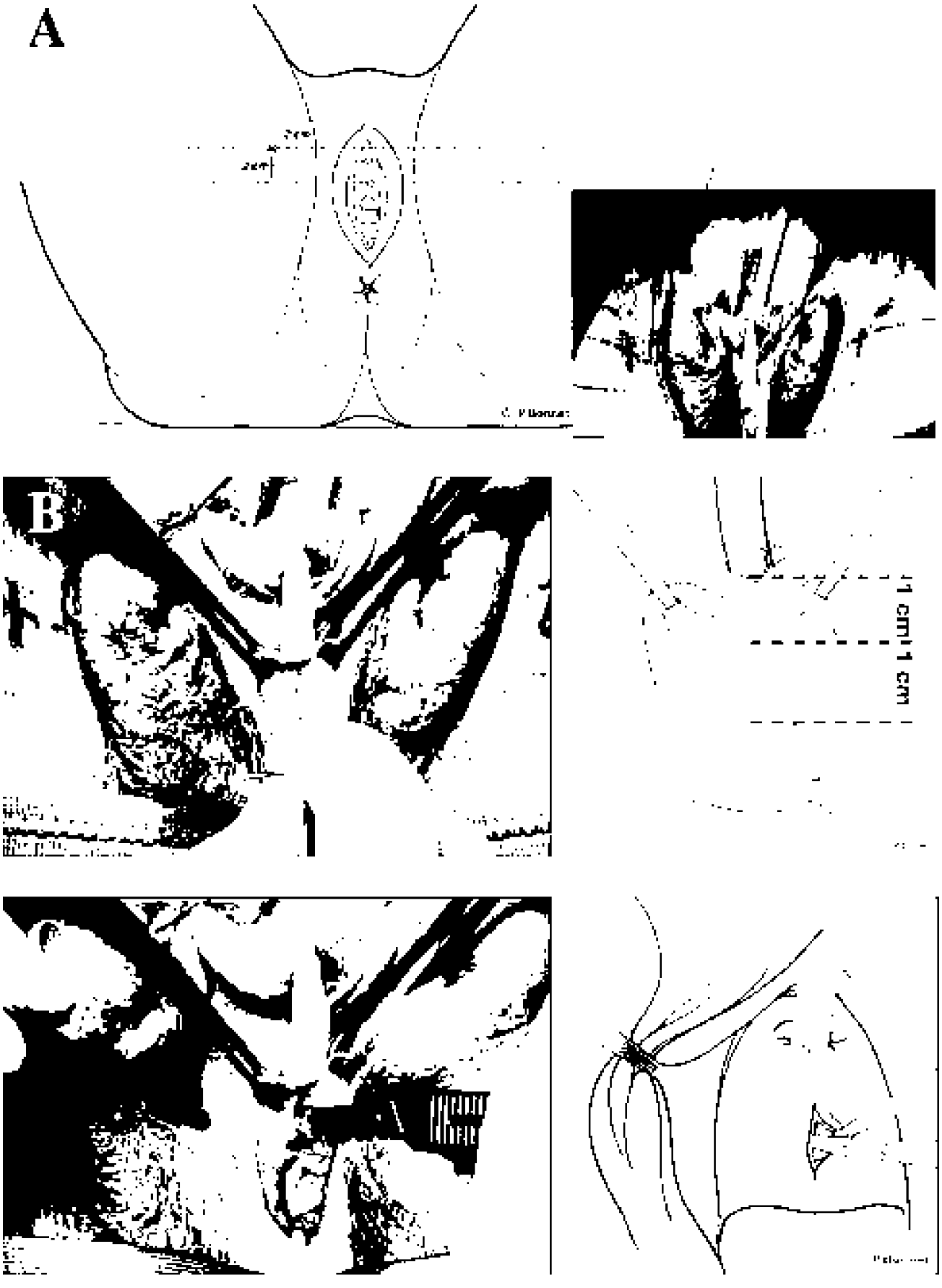
We believe that our revised version of the manuscript now incorporates the answers to the criticisms of the reviewers, clearly emphasizes the limitations of our study (methodology and short follow-up), and is formatted to the New Surgical Technique section of European Urology.

We hope you will find our manuscript acceptable for publication as a New Surgical Technique in European Urology.

Thank you for your consideration of this manuscript.

Jean de Leval, MD, PhD

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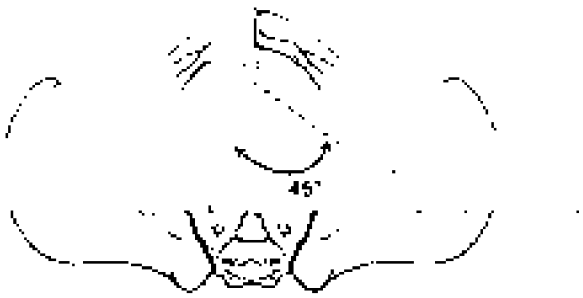

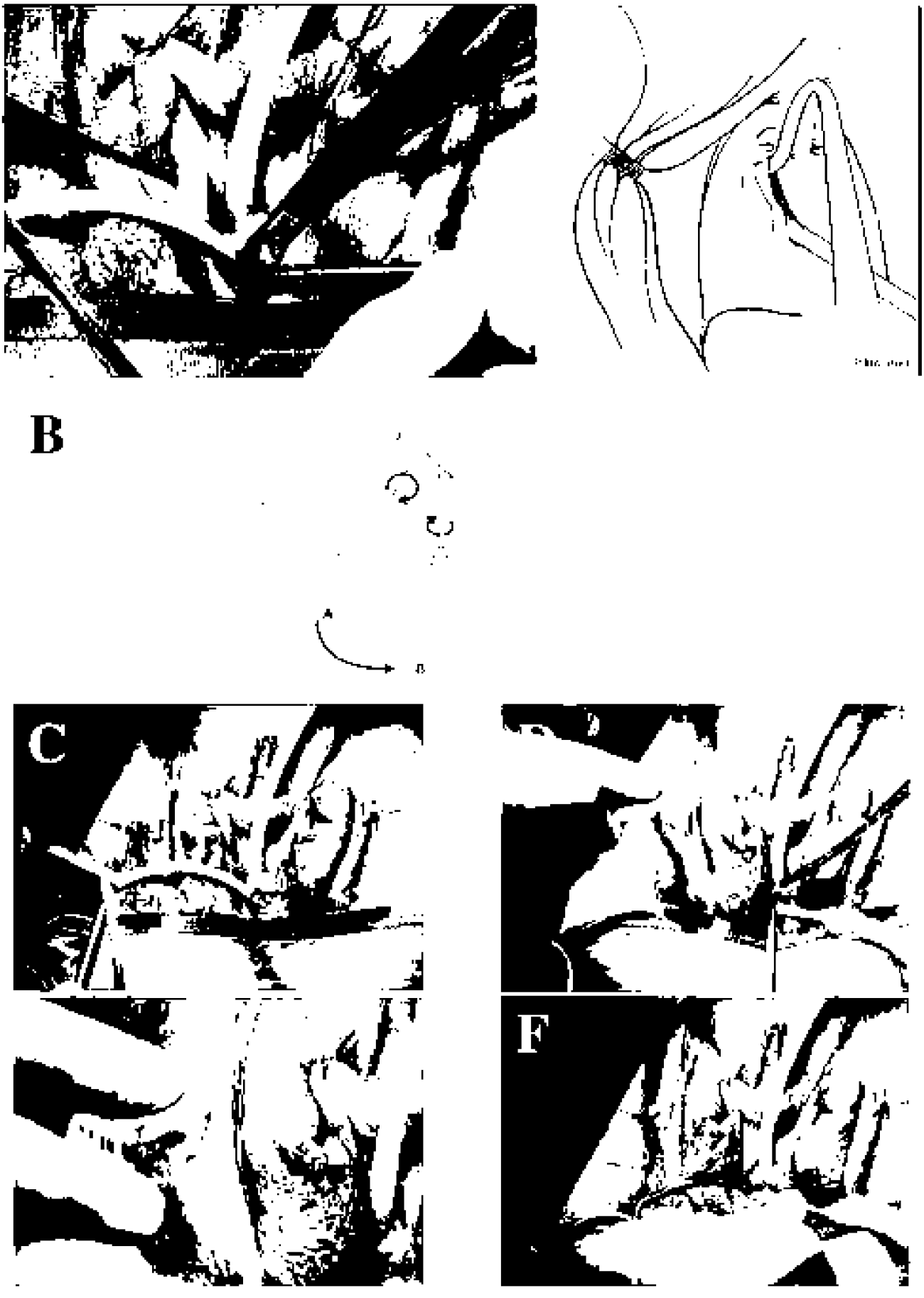
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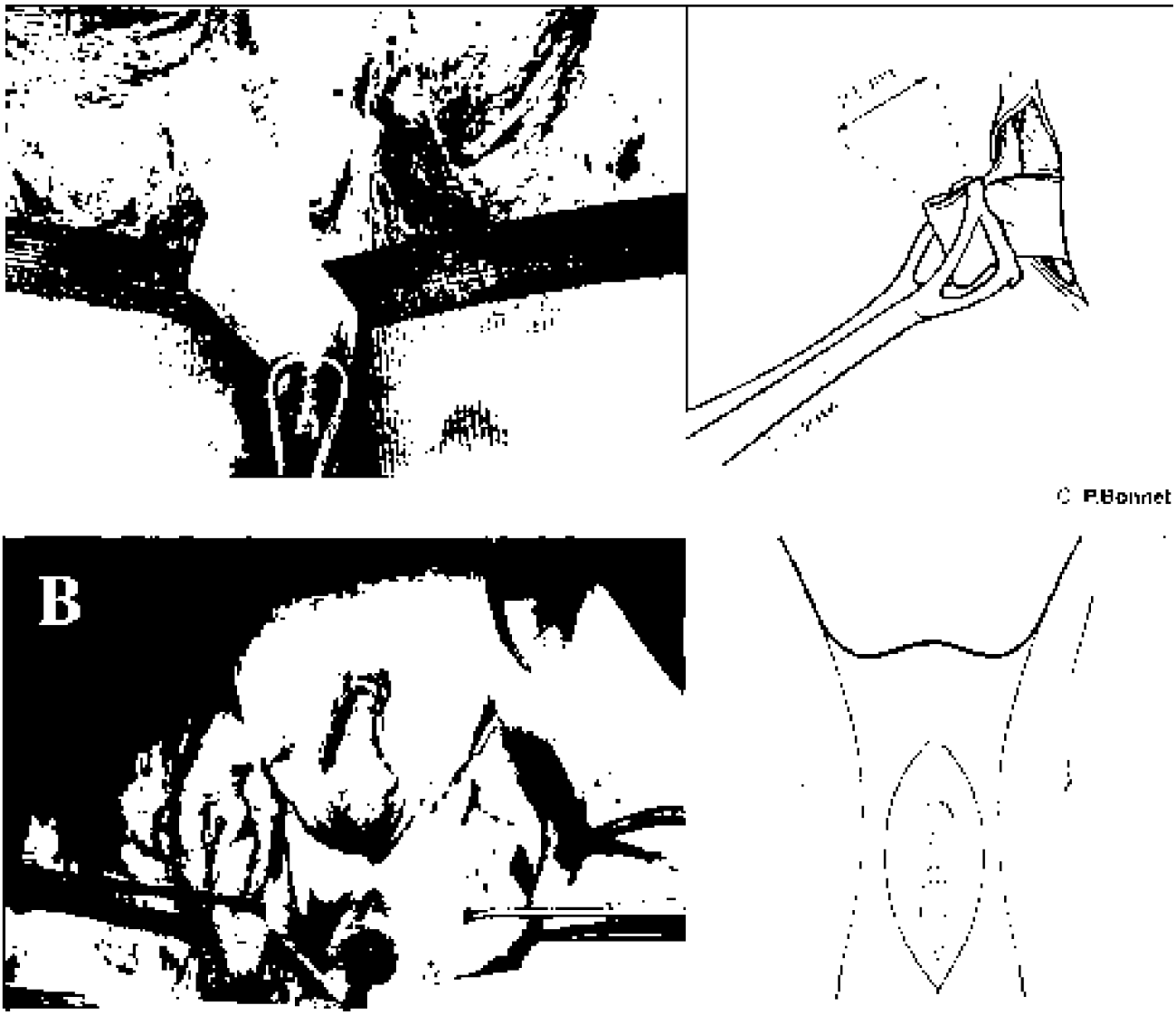
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